**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | | |
|---|---|---|
| **UNITED STATES OF AMERICA, et al., ex rel. CHARLES STRUNCK, et al.,** | : | |
| **Plaintiffs,** | : | |
| **v.** | : | **Civil Action No. 12-CV-0175** |
| **MALLINCKRODT ARD LLC. (f/k/a Mallinckrodt ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.),** | : | |
| **Defendant.** | : | |
| **UNITED STATES OF AMERICA, et al., ex rel. SCOTT CLARK,** | : | |
| **Plaintiffs,** | : | |
| **v.** | : | **Civil Action No. 13-CV-1776** |
| **MALLINCKRODT ARD LLC. (f/k/a Mallinckrodt ARD, Inc.; f/k/a Questcor Pharmaceuticals, Inc.),** | : | |
| **Defendant.** | : | |

A TRUE COPY CERTIFIED FROM THE RECORD
DATED: JUN - 4 2019
ATTEST: Steve Tomas
DEPUTY CLERK UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

## UNITED STATES' COMPLAINT IN INTERVENTION

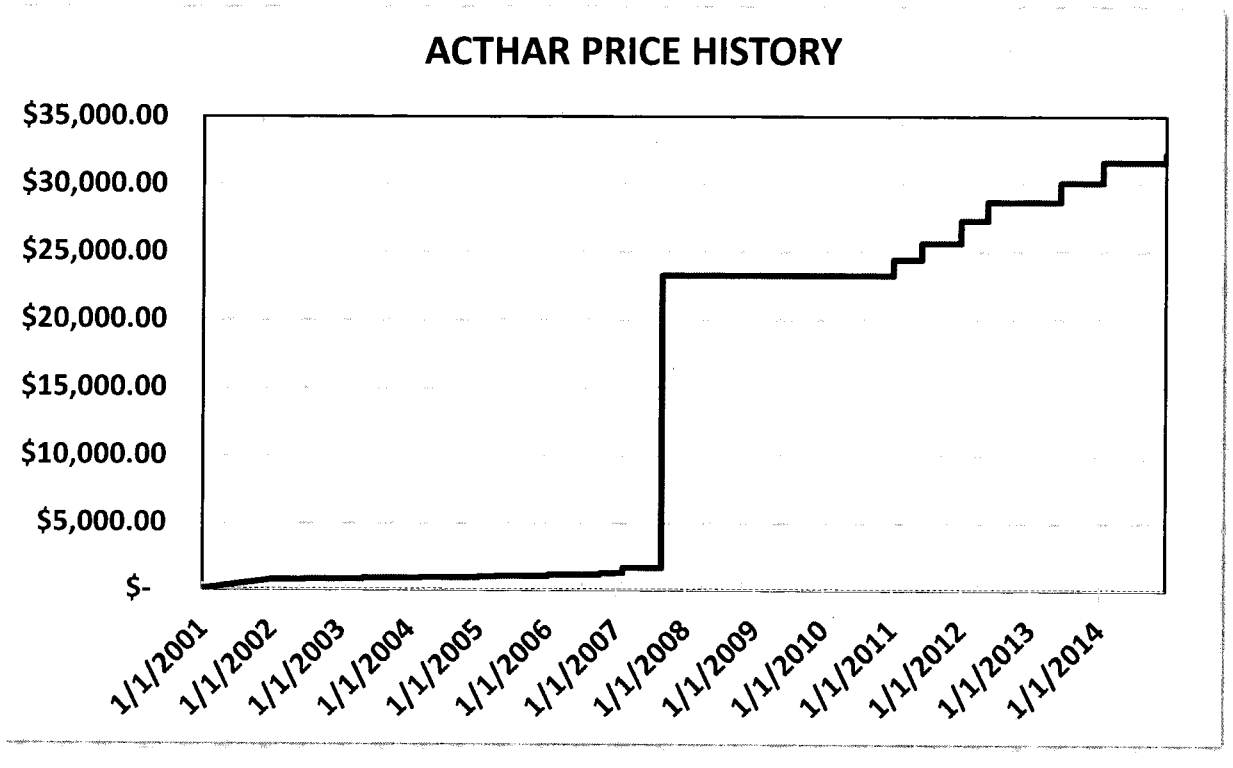
By notice to the Court on March 6, 2019, the United States of America intervened in the above-captioned cases. The United States alleges as follows:

## INTRODUCTION

1. The United States of America ("United States") brings this action against Defendant pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), seeking treble damages and civil penalties.

2. From 2010 through 2014 ("relevant time period"), Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD, Inc. and previously Questcor Pharmaceuticals, Inc.) (collectively "Mallinckrodt," the "Defendant," or the "Company") knowingly paid illegal kickbacks in the form of copayment subsidies for its drug Acthar Gel (also referred to as H.P. Acthar Gel) (collectively "Acthar"). The scheme allowed the Company to continually raise Acthar's price yet market it as "free" to patients and doctors, shifting the drug's ever-increasing cost to Medicare. As a result of its conduct, Mallinckrodt caused the submission of millions of dollars in false Medicare claims for Acthar.

3. Mallinckrodt did not develop Acthar. The U.S. Food and Drug Administration ("FDA") first approved Acthar in the 1950s, and Mallinckrodt acquired it in 2001. From the time of the acquisition until December 2014, Mallinckrodt raised Acthar's per-vial price from approximately $50 per 5 milliliter vial to over $32,200 per vial:



4. Mallinckrodt knew that the cost of Acthar would make it difficult to sell because there were cheaper, effective competitor drugs available to treat certain of its approved uses, namely acute exacerbations in multiple sclerosis, lupus, and rheumatoid arthritis. Mallinckrodt intended to overcome this difficulty and did so by making the drug "free" to patients by subsidizing their Medicare copayments. By doing so, Mallinckrodt could maintain the high price of Acthar to maximize its own sales revenues, but minimize the risk that the drug's high price would impede doctors and patients from using it.

5. Mallinckrodt knew that paying copay subsidies to Medicare patients was illegal. To achieve the same end indirectly, Mallinckrodt paid copay subsidies through a foundation that Mallinckrodt used as a conduit to do so. At the foundation, called the Chronic Disease Fund (now d/b/a Good Days) (collectively "CDF"), Mallinckrodt designed supposed "patient assistance" funds that paid copays for Acthar only and then funded them through "donations," knowing its money would be used on Acthar copays to the exclusion of other drugs. Mallinckrodt then sent Medicare patients to CDF in order to receive virtually guaranteed, Mallinckrodt-funded subsidies. The Company also obtained and used data about the number patients at CDF, the subsidies paid to them, and the amount of money Mallinckrodt needed to pay to keep covering their Acthar copays. Mallinckrodt financed the funds accordingly. Mallinckrodt also marketed the drug as "free" because of the copay funds it set up. Finally, the Company excluded financially-needy patients with Medicare coverage for Acthar from its own free product program in favor of sending those patients to CDF for copay subsidies to induce Medicare claims and, thus, generate a sale of the drug for Mallinckrodt.

6. Using the CDF Funds as a conduit to pay illegal copay subsidies was profitable for Mallinckrodt. For example, at a time when Acthar cost $30,000, Mallinckrodt could spend

$1,500 to subsidize a five percent Medicare copay knowing that it would reap as much as $28,500 in sales revenue from that prescription.

7. Mallinckrodt's scheme circumvented the Congressional design of the Medicare system, which requires a copay, in part, to act as a market constraint against increasing drug prices. Instead, Mallinckrodt left American taxpayers to shoulder the drug's ever-increasing cost, while the Company reaped for itself the resulting profits.

## JURISDICTION, VENUE, PARTIES

8. This action arises under the FCA, as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1345 and 1367(a).

9. Venue is proper in the Eastern District of Pennsylvania pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

10. This Court may exercise personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) and because Defendant transacts business in this District.

11. Plaintiff, the United States of America, brings this action on behalf of the Department of Health and Human Services ("HHS"), and, specifically, its operating division, the Centers for Medicare & Medicaid Services ("CMS").

12. Relator Charles Strunck is an individual who resides in the State of New York. Relator Strunck was employed by Mallinckrodt from September 2010 until August 2011 as an Acthar sales specialist with responsibility for sales in the States of New York and Connecticut. Relator Lisa Pratta is an individual who resides in the State of New Jersey. Relator Pratta was employed by Mallinckrodt from September 2010 through June 17, 2017 as an Acthar sales specialist with responsibility for sales in New Jersey. On January 20, 2012, Relators Strunck and Pratta filed *United States, et al., ex. rel. Strunck v. Questcor Pharm., Inc.*, Civil Action No. 12-

175 (BMS) (E.D. Pa.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

13. Relator Scott Clark is an individual who resides in the state of Oregon. Mr. Clark was employed by Mallinckrodt from September 2010 until June 2012 as an Acthar sales specialist with responsibility for the State of Oregon. On April 4, 2013, Relator Clark filed *United States, et al., ex. rel. Clark v. Questcor Pharm., Inc.*, Civil Action No. 13-cv-01776 (BMS) (E.D. Pa.), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b).

14. Defendant Mallinckrodt ARD LLC has its principal place of business at 1425 U.S. Route 206, Bedminster, NJ, 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and, prior to that, was named Questcor Pharmaceuticals, Inc. ("Questcor").

15. Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt plc, an Irish public limited company. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and effectuated the acquisition of Questcor on August 14, 2014.

16. Questcor survived the merger as a wholly owned indirect subsidiary of Mallinckrodt plc and continued to market Acthar thereafter, until changing its name to Mallinckrodt ARD, Inc. on July 27, 2015.

17. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and continues to market Acthar under that name now.

18. Mallinckrodt has marketed Acthar in the United States at all relevant times for purposes of this complaint-in-intervention. Mallinckrodt conducts business nationwide.

## LEGAL BACKGROUND

### I. THE MEDICARE PART D PROGRAM AND COPAYS UNDER MEDICARE PART D

A. Medicare Part D

19. Congress established Medicare in 1965 to provide health insurance coverage for people aged sixty-five or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395 *et seq*.

20. Medicare is funded by the federal government and administered by CMS, which is part of the United States Department of Health and Human Services ("HHS").

21. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan Sponsors, to administer prescription drug plans. *See* 42 C.F.R. § 423.4.

22. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. An individual is eligible to enroll in Medicare Part D if the individual lives in the service area of a Part D plan and is entitled to Medicare benefits under Medicare Part A or enrolled under Medicare Part B. *See* 42 C.F.R. § 423.30(a).

23. The Part D Sponsors are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into subcontracts with pharmacies, or other "downstream entities," to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

24. These entities submit claims to Part D plans that pay for the drug using funds provided by CMS from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

B. Medicare Part D Copay Obligations

25. By Congressional design, under the Medicare statute, a Part D beneficiary may be required to make a partial payment for the cost of these prescription drugs in the form of a "copayment," "coinsurance," or "deductible" (collectively "copays"). These copay obligations can be substantial for expensive medications and vary throughout the year, depending on a beneficiary's total Part D covered expenses incurred that year up to that point. *See* 42 U.S.C. § 1395w-102. For example, after meeting an annual deductible (originally $250 in 2006), the standard Part D benefit requires a 25 percent patient copay up to an "initial coverage limit" (originally $2,250 in 2006). *Id.* at b(1)-(2).

26. After meeting the "initial coverage limit," during all relevant times, patient copay obligations increased substantially prior to meeting an "annual out-of-pocket threshold" for the coverage year. This period exceeding the "initial coverage limit" and before crossing the "annual out-of-pocket threshold" is referred to as the "coverage gap." *See* 42 U.S.C. § 1395w-102(b)(2)(D). For brand name drugs, the patient copay owed in the "coverage gap" was 100 percent through 2010, 50 percent in 2011 and 2012, and 47.5 percent in 2013 and 2014.

27. The financial thresholds for the "deductible," "initial coverage limit," and annual "out-of-pocket threshold" have increased each year since 2006 pursuant to a statutory and regulatory formula (from $250, $2,250, and $3,600 respectively to $310, $2,850, and $4,700 respectively by 2014).

28. Medicare Part D coverage for costs incurred after the "coverage gap", *i.e.*, on costs incurred for the remainder of the benefit year above the "annual out-of-pocket threshold" (originally $3,600 in 2006), is commonly referred to as "catastrophic coverage."

29. Congress determined that patients owe a copay obligation in the "catastrophic coverage" phase equaling the greater of: 1) five percent of the prescription drug costs; or 2) a small fixed dollar amount (originally $5 for brand name drugs in 2006). 42 U.S.C. § 1395w-102(b)(4). As a practical matter, a patient will owe a five percent copay in the "catastrophic coverage" phase of Part D for any expensive, brand name drug. As described below, the remaining costs are paid by a "reinsurance subsidy" from CMS (80 percent) and the Part D plans (15 percent).

30. These Medicare copays exist to encourage physicians and beneficiaries to be efficient consumers of federally reimbursed health care products, while also encouraging those manufacturing such products to price them based on market forces such as consumer sensitivity and competition. Manufacturers paying the Medicare copays of those seeking to buy their drug circumvent this congressionally designed check on health care costs. As the United States Department of Health and Human Services, Office of the Inspector General ("HHS-OIG") has observed, drug manufacturers paying the Medicare Part D copays of patients taking their products "eliminat[e] a market safeguard against inflated prices." HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005) ("2005 SAB").

## II. THE FALSE CLAIMS ACT

31. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]

> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . .is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

32. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

33. The FCA defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

*Id.* at § 3729(b)(2).

34. For purposes of the FCA, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

## III. THE ANTI-KICKBACK STATUTE

35. The Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions would result in goods and services being provided that are excessively costly, medically unnecessary, of poor quality, or potentially harmful to patients. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a *per se* prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback gave rise to overutilization or poor quality of care. In particular, when determining what conduct to prohibit, Congress determined that the inducements at issue would "contribute significantly to the cost" of federal health care programs absent federal penalties as a deterrent. H.R. Rep. No. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056.

36. The AKS was first enacted in 1972, and was strengthened in 1977, 1987, and 2010, to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93; Patient Protection and Affordable Care Act, Pub. L. No. 111-148. In adopting and strengthening the AKS repeatedly, Congress sought to "strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs." H.R. Rep. No. 95-393, at 1 (1977).

37. The AKS is a federal criminal statute that prohibits any person or entity from knowingly and willfully offering or paying anything of value (including money), directly or

indirectly, overtly or covertly, to any person to induce that person to purchase or refer federally-funded medical goods or services, including prescription drugs covered by Medicare.

38. Violation of the AKS is a felony and can also subject the perpetrator to criminal penalties, exclusion from participation in federal health care programs, and civil monetary penalties. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

39. In pertinent part, the Anti-Kickback Statute provides:

> (b) Illegal remunerations . . .
>
> > (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
> >
> > > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > >
> > > (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
> >
> > shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2).

40. The AKS defines remuneration to include anything of value, including "cash" and "in-kind" payments or rebates. 42 U.S.C. § 1320a-7b(b)(2). Money and other forms of financial subsidies that can be used to pay or waive Medicare copays constitute remuneration under the AKS.

41. The AKS defines a "Federal health care program" to mean "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government," except for the health insurance

program for federal employees under 5 U.S.C. §§ 8901 *et seq*. 42 U.S.C. § 1320a-7b(f). Medicare is a "Federal health care program" for purposes of the Anti-Kickback Statute.

42. The AKS provides that: "With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section." 42 U.S.C. § 1320a-7b(h).

43. The AKS further provides that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from violations of the AKS are per se false or fraudulent within the meaning of 31 U.S.C. § 3729(a). Accordingly, a person violates the FCA when he or she knowingly submits or causes to be submitted claims to federal health care programs that result from violations of the AKS.

44. Compliance with the AKS is material to the agency's decision to pay a Medicare claim.

45. As set forth in more detail below, Mallinckrodt knowingly and willfully paid remuneration to Medicare patients to induce the patients to purchase Acthar by providing them with financial subsidies to satisfy the copayment obligations necessary to buy the drug (which were often significant for Medicare patients, because of the price Mallinckrodt set for Acthar). At least one purpose of the remuneration in the form of copay subsidies was to induce patients and doctors to use and purchase Acthar.

46. By providing kickbacks to induce prescriptions for and purchases of Acthar that were reimbursed by Medicare, Mallinckrodt knowingly caused false claims to be submitted to Medicare for Acthar.

## FACTUAL BACKGROUND

### I. BACKGROUND ON MULTIPLE SCLEROSIS, LUPUS, AND RHEUMATOID ARTHRITIS

A. Multiple Sclerosis

47. Multiple sclerosis ("MS") is a central nervous system disease in which the body's immune system attacks the body's myelin nerve cell coating. MS can cause a variety of symptoms, which can increase in severity periodically.

48. MS "relapses," "acute exacerbations," or "flares" (collectively "MS exacerbations") are temporary periods of increased disease activity in an MS patient, manifested by the worsening of existing MS symptoms or the onset of other MS symptoms. MS exacerbations are not a separate disease from MS.

49. The FDA has approved several medications for the long term treatment of MS patients, including medications to slow the accumulation of physical disability from the disease or to decrease the frequency of acute exacerbations. These medications are sometimes referred to as MS "disease modifying" drugs or therapies. Acthar is not a "disease modifying" drug or therapy for MS.

50. The FDA also has approved drugs for treatment of MS exacerbations, such as Acthar. A standard treatment for MS exacerbations includes administering methylprednisolone, a steroid, which can be administered intravenously ("IVMP") or orally. Both IVMP and oral methylprednisolone are available in several brand name or generic forms. The drugs are significantly less expensive than Acthar.

B. Lupus

51. Systemic lupus erythematosus ("Lupus") is an autoimmune disease in which the body's immune system targets its own healthy cells. Lupus can damage the kidneys, brain, skin, joints, or other areas of the body.

52. Lupus patients can experience "flares" or "exacerbations" (collectively "Lupus exacerbations"), which are periods of increased disease activity and are characterized by worsening Lupus symptoms.

53. Lupus exacerbations are not a separate disease from Lupus.

54. A standard treatment for Lupus exacerbations includes the administration of steroids, which can be available in brand name or generic forms. The drugs are significantly less expensive than Acthar.

C. Rheumatoid Arthritis

55. Rheumatoid Arthritis ("RA") is an inflammatory autoimmune disease in which the body's immune system targets itself, including the joints. RA patients can experience "flares" or "exacerbations" (collectively, "RA exacerbations"), which are periods of increased disease activity and are characterized by worsening RA symptoms.

56. RA exacerbations are not a separate disease from RA.

57. A standard treatment for RA exacerbations includes the administration of steroids, which can be available in brand name or general forms. The drugs are significantly less expensive than Acthar.

## II. BACKGROUND ON ACTHAR GEL

58. Acthar is an adrenocorticotrophic hormone analogue that is injected either beneath the skin (subcutaneously) or into the muscle (intramuscularly), depending on its use.

59. The U.S. Food and Drug Administration approved Acthar for marketing in the United States in 1952, after the pharmaceutical division of a large meatpacking and food processing company invented the drug in 1948. Acthar's active ingredient is extracted from pig pituitary glands.

60. According to its FDA label, once injected, Acthar may stimulate the body to secrete certain hormones (such as cortisol and corticosterone). According to Mallinckrodt's website, "the exact way Acthar works is unknown," but it is "believed to work" by helping the body "produce its own natural steroid hormones" and by affecting the body's immune cells to have an "impact" on inflammation.

61. Acthar's FDA label contains an approval for the treatment of MS as follows: "Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease."

62. Acthar's FDA label also contains an approval for "Collagen Diseases," including Lupus. It is FDA-approved for treatment "[d]uring an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)."

63. Acthar's FDA label also contains an approval for "Rheumatic Disorders," "[a]s adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: [p]soriatic arthritis, [r]heumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), [a]nkylosing spondylitis."

64. In 2010, the FDA approved Acthar to treat a rare seizure disorder afflicting children called infantile spasms ("IS").

## III. MALLINCKRODT ACQUIRED ACTHAR, RAISED ITS PRICE TO OVER $23,000 PER VIAL, AND STOPPED MARKETING IT FOR MS

65. In July 2001, Mallinckrodt acquired worldwide rights to sell and manufacture Acthar from another drug company, Aventis Pharmaceuticals, Inc.

66. Mallinckrodt began to market Acthar in the third quarter of 2001 and initially increased its price from approximately $50 per vial to nearly $750 per vial. It quickly became the Company's main product, accounting for 94 percent of Mallinckrodt's net sales by the end of 2006.

67. During this time period, the majority of Acthar sales came from referrals for IS patients by pediatric neurologists, although the Company did promote Acthar to adult neurologists for use on MS patients as well. MS usage accounted for about one-third of Acthar referrals until 2007.

68. In 2007, Mallinckrodt adopted a so-called "orphan pricing strategy" that purportedly focused on positioning Acthar as a preferred therapy for IS, sharply increasing its price, and pivoting away from marketing Acthar for MS or other more common diseases.

69. On August 27, 2007, Mallinckrodt increased the cost of Acthar to over $23,000 per 5 milliliter vial. This represented an increase of over 46,000 percent from Acthar's approximately $50 price when Mallinckrodt acquired it six years earlier.

70. Mallinckrodt settled on this per-vial price because it wanted the new cost of an average Acthar regimen for IS to be approximately $100,000.

71. In choosing this new per-vial price, Mallinckrodt initially believed that it had priced Acthar out of the MS exacerbation treatment market, which has many low-cost treatment options. The Company believed the new price of Acthar would "negate any business potential

Acthar had in MS." Mallinckrodt terminated its MS sales force and dedicated remaining account representatives to work with IS prescribers.

72. By the end of 2007, Mallinckrodt's net sales increased to $49.8 million, from $12.8 million the year before. As the Company expected, MS referrals declined to an all-time low of just eight vials in December 2007 (compared to an average of 250 vials per month prior to the 2007 price increase).

## DEFENDANT'S FRAUD SCHEME

73. Mallinckrodt soon realized that it could generate significant revenue if it could successfully sell Acthar as an MS treatment at the new $23,000 per vial price.

74. Mallinckrodt also knew that the new price was a barrier to those sales, given the wide availability of less expensive alternatives and the lack of scientific data showing that Acthar was more effective than those alternatives.

75. But Mallinckrodt soon determined that, if it subsidized Acthar copays, it could market the drug as "free" to doctors and patients, while payers such as Medicare absorbed the drug's increased cost.

76. Rather than provide these illegal subsidies directly, Mallinckrodt routed them through a foundation, CDF. CDF is headquartered in Plano, Texas, and operates funds that receive payments from donors and uses those payments to pay copay subsidies to patients, including Medicare patients in this judicial district.

77. Mallinckrodt established funds at CDF and made payments to them, intending for all of its funding to be used to subsidize the copays for Acthar but no other drug.

78. Mallinckrodt then sent patients to CDF and actively tracked the status of every referral. Mallinckrodt made continued payments to the funds in amounts necessary to keep subsidizing the Acthar copays of patients the Company sent there.

79. As Mallinckrodt implemented this scheme, its Acthar sales and revenue grew significantly and Mallinckrodt believed the subsidies it routed through CDF were the "most motivating factor" to "[d]rive Acthar [p]rescribing" in the face of concerns about Acthar's cost. With a proven method to negate these concerns, Mallinckrodt raised Acthar's price to over $32,000 per 5 milliliter vial by the end of 2014.

## I. MALLINCKRODT REALIZED IT COULD INCREASE ITS ACTHAR PROFITS BY UNLAWFULLY SUBSIDIZING ACTHAR COPAYS

80. Not long after raising Acthar's price to over $23,000 per vial in 2007 and believing, at least initially, that it had priced itself out of the MS market, Mallinckrodt saw that the market potential of successfully selling Acthar as an MS treatment at the new price would be hundreds of millions of dollars. Mallinckrodt re-established a pilot MS sales force in 2008 to try to generate Acthar MS referrals at the new price.

81. Mallinckrodt knew that Acthar had many cheaper, effective competitors in the MS exacerbation treatment market. For example, according to Mallinckrodt, IVMP was "far and above [the] market leader in acute exacerbation therapy," and "[t]he price of Acthar compared to the relative ease and convenience of a three-day, generic IVMP infusion . . . creates a significant barrier" with MS physicians. Mallinckrodt further knew that, while "the retail price for an average course of Acthar based upon the labeled 2-3 week dosing (2 vials) is approximately $50,000," the "standard treatment with IVMP [] ranges anywhere from $400-$1,200" and "this disparity in price is compounded by the lack of scientific evidence to support significant clinical

advantages in flare treatment." Mallinckrodt also knew that, in some instances, low-cost, oral steroids were also "becoming an attractive option in the treatment of MS flares."

82. Mallinckrodt also understood that, for some insurance plans, the over-$23,000 price could lead to very high patient costs. Medicare Part D beneficiaries, in particular, could owe thousands of dollars in copays for one vial of Acthar while advancing through the deductible, initial coverage limit, and coverage gap. Even in the catastrophic coverage stage of Part D copays, Acthar patients would owe five percent of the drug's cost (*i.e.*, more than $1,150 per vial).

83. Mallinckrodt realized subsidizing patient copay obligations could overcome some doctor and patient cost concerns.

84. Mallinckrodt knew that it was illegal to subsidize Medicare copays directly, so it sought to accomplish the same result through a "copay assistance fund" that it designed, created, and used as a money conduit to pay patient copay subsidies for Acthar (but no other drug).

85. Mallinckrodt initially attempted this by providing funding to a foundation called the National Organization for Rare Disorders ("NORD"). In particular, Mallinckrodt hoped to use NORD to subsidize Acthar copays on a large scale (to match its ramped-up marketing efforts), and the Company wanted detailed data confirming that its payments were being spent on Acthar copays (and not other drugs).

86. Mallinckrodt did not think that NORD effectively served the Company's purposes. In the spring of 2010, Mallinckrodt decided to switch from NORD and began to look elsewhere for an organization that, in Mallinckrodt's opinion, better serve its desires. The individuals involved in making this determination included: 1) a Senior Manager of Specialty Distribution and Support Services in Mallinckrodt's Reimbursement Division ("Reimbursement

Manager"); 2) a full time consultant that Mallinckrodt hired from an entity called BioSolutia to work with Mallinckrodt regarding NORD and other Acthar reimbursement issues ("BioSolutia Consultant"); 3) Mallinckrodt's Vice President of Commercial Operations ("Commercial VP"); and 4) Mallinckrodt's then-Executive Vice President and Chief Business Officer, whose title changed to Chief Operating Officer the next year ("Mallinckrodt's COO").

87. After discussions, in April and May 2010, these individuals agreed that the BioSolutia Consultant would contact CDF to discuss starting a new fund for Mallinckrodt to replace the copay fund at NORD.

## II. MALLINCKRODT ESTABLISHES ITS ACTHAR COPAY CONDUIT AT CDF

### A. The MS "Acute Exacerbation" Fund

88. On May 27, 2010, the BioSolutia Consultant emailed Mallinckrodt's COO, Commercial VP, and Reimbursement Manager that: "As promised, I spoke with [the President of CDF] this morning and described our potential need and situation re: MS Exacerbation Copay Fund." The BioSolutia Consultant explained that CDF already had a patient assistance fund for MS patients, but that CDF's President "thought we would be able to comfortably define the fund as specific to MS exacerbation, as we've done at NORD, to prevent chronic MS med needs from tapping the funds." This was important to Mallinckrodt because the Company did not want to make payments to a fund that might pay the copays of MS drugs other than Acthar.

89. Mallinckrodt's COO responded to the BioSolutia Consultant the same day: "This sounds like a good possibility" and asked to schedule a meeting with CDF. The BioSolutia Consultant wrote back to CDF: "Thanks for discussing [Mallinckrodt]'s needs re: MS Exacerbation Copay Assistance fund with me today" and added that he would provide CDF with dates for an introductory meeting. He also explained that Mallinckrodt expected to pay an

increasing amount of Acthar Medicare copays going forward: "In 2009 the fund generated about $450K in needs and in 2010 it is tracking about 20% above that since most are Med-D with percentage (specialty tier) copays."

90. On June 1, 2010, after subsequent discussions with Mallinckrodt, CDF gave a presentation to Mallinckrodt's COO and other employees demonstrating CDF's operational "capabilities" to meet this ramped up demand. In an e-mail to Mallinckrodt's Reimbursement Manager that evening, the BioSolutia Consultant noted that, after the presentation, Mallinckrodt's COO viewed the choice between NORD and CDF as "Mom & Pop vs. WalMart."

91. Within two weeks, Mallinckrodt decided that it needed a "WalMart" copay fund to operationalize its scheme on a larger scale. As Mallinckrodt's COO wrote to Mallinckrodt's CEO on June 18, 2010:

> We have made the decision to move the co-pay programs to the Chronic Disease Fund from NORD. . . . In short, we are at the point where we have outgrown NORD's "mom-and-pop" co-pay capabilities, and this change will give us a much better understanding of flow of funds and flexibility regarding how co-pay funs [*sic*] are made available.

92. At the same time, Mallinckrodt held discussions with CDF to finalize the establishment of the new "MS Acute Exacerbation Fund." Mallinckrodt set up the fund for just patients with government insurance, such as Medicare Part D.[1]

93. Mallinckrodt and CDF agreed that the MS Acute Exacerbation Fund would cover the copays of Acthar but not the copays of other drugs. For example, on July 9, 2010, CDF sent Mallinckrodt a "Program Spec[ification]" term sheet, making the Acthar-specific nature of the

[1] For patients with private insurance, Mallinckrodt had CDF open a separate Acthar "Private Fund" for Mallinckrodt to send private insurance patients to CDF to have Acthar copays paid. That fund also exclusively covered Acthar.

fund clear. The document, entitled "HPActhar_ProgramSpecs" stated that the "Product = H.P. Acthar Gel" for the "public" MS Acute Exacerbation Fund.

94. Mallinckrodt sent an executed copy of the donation agreement for the MS Acute Exacerbation Fund to CDF on July 14, 2010.

95. The MS Acute Exacerbation Fund agreement contained multiple statements that were known to be false at the time they were made. For example, the agreement stated the fund would provide financial assistance, including copay assistance, to "patients being treated for acute exacerbations of multiple sclerosis with any medically appropriate therapy[.]" In reality, and as Mallinckrodt intended and demanded, the MS Acute Exacerbation Fund paid copays for Acthar exclusively.

96. The donation agreement also falsely stated that CDF already operated "an assistance program for patients being treated for acute exacerbations of multiple sclerosis . . . [and Mallinckrodt] desires to provide [CDF] with a donation for [it]." At that time, CDF did not have such an assistance program; the fund was established at the behest of Mallinckrodt, and Mallinckrodt viewed the fund as its own.

97. The agreement also stated that the Program "eligibility criteria will be developed by the Board [of CDF] without consideration or input by Donor." In fact, the decision that only Acthar patients were eligible was dictated by Mallinckrodt.

98. Key individuals at Mallinckrodt agreed and shared the view that the fund was established and controlled by Mallinckrodt and exclusively available to Acthar patients. For example:

- In an email from Mallinckrodt's COO to CDF's Senior Director of Operations on July 15, 2010—telling her to expect Mallinckrodt's first payment the next day—Mallinckrodt's COO wrote: "I have notified NORD's President . . . that we have now

established co-pay funds at CDF to help address out [sic] expanding needs for patient support and monitoring of funding flows." (Emphasis added.)

- On July 21, 2010, the BioSolutia Consultant wrote to several specialty pharmacies, copying the Mallinckrodt Reimbursement Manager, that "[Mallinckrodt] will be adding [CDF] as an administrator/source of funding for their copay assistance programs for Acthar." (Emphasis added.)

- On October 19, 2010, the Reimbursement Manager wrote to the sales force again that: "Please be sure that your offices are aware of our Copay Assistance Program" and reminded them that "a key point to cover when discussing copay assistance" is that "[Mallinckrodt] established an Acute Exacerbations of Multiple Sclerosis 'bucket'. As a result, Acthar patients needing copay assistance will not be using funds provided by the manufacturers of the disease modifying therapies." (Emphases added.)

- On October 26, 2011, the Reimbursement Manager wrote to the Executive Director of CDF in an email titled "[Mallinckrodt] copay funds" to schedule a discussion about future payments to CDF and "operational things." (Emphasis added.)

- On January 15, 2012, the Reimbursement Manager wrote to the Commercial VP about the need for more payments to CDF: "I anticipate a higher demand on our copay funds this month because most Med-D patients will need coverage for the donut hole because everything reset on January 1st." (Emphasis added.)

99. On July 15, 2010, Mallinckrodt's COO approved a wire transfer for $150,000 from Mallinckrodt to CDF to fund the MS Acute Exacerbation Fund and Private Fund. CDF received the wire on July 16, 2010, and the MS Acute Exacerbation fund opened at that time. From this point through 2014, the MS Acute Exacerbation Fund paid Medicare copays for Acthar but not for any other drug.

100. Mallinckrodt sent patients to CDF via the Company's "reimbursement hub" for Acthar, called the Acthar Support and Access Program ("ASAP"). Mallinckrodt controlled ASAP, which included a call-center that received referrals for Acthar from physician offices and patients. Mallinckrodt's sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so the Company could track them. After a referral came in to ASAP, as

discussed in more detail below, ASAP provided patients with an "automatic offering" of copay assistance via CDF.

101. Although the new fund was ostensibly defined as limited to MS "Acute Exacerbation" patients to ensure that Mallinckrodt's payments to it would not be used on other MS drugs that are prescribed for long-term disease treatment, Mallinckrodt never intended to place any such limitation on Acthar patients.

102. Instead, Mallinckrodt, via ASAP, referred Acthar patients to the fund regardless of whether they were using the drug for an acute exacerbation or on a long-term basis. Internally, Mallinckrodt referred to this longer-term use of Acthar in MS patients as "pulse maintenance" or "pulse" therapy.

103. Mallinckrodt acknowledged this to be an unapproved use of Acthar, took steps internally to identify which Acthar prescriptions were for such "pulse" treatments, and knew it accounted for a significant number of Acthar refills. As stated in an analysis of refill patterns prepared for the Commercial VP on October 24, 2011, for example: "Take a look at the attached spreadsheet. I think a significant percentage of refills are attributed to pulse like treatment." Through the MS Acute Exacerbation fund, Mallinckrodt sometimes paid patients' recurring copay subsidies for years' or months' worth of Acthar referrals.

104. As Mallinckrodt expanded its Acthar marketing beyond MS, it repeated this same scheme in two other areas: Lupus and Rheumatoid Arthritis.

B. The Lupus "Exacerbation" Fund

105. Mallinckrodt began planning to market Acthar for Lupus in mid-2011 and assumed that it needed to subsidize Medicare copays to induce sales of Acthar for Lupus as it

had for MS. Mallinckrodt thus set about to establish a purported Lupus "exacerbation" fund that the Company could use as a conduit to subsidize Lupus patients' Medicare copays for Acthar.

106. On July 6, 2011, Mallinckrodt's Reimbursement Manager wrote the COO:

> After our recent discussions about lupus, it occurred to me that we will need to create copay fund at CDF for this disease state. It would make sense to start the fund with a minimal amount of money until we can determine the referral volume for that diagnosis. I'm not sure how soon we can expect to see a referral but we will want to have the fund in place as soon as we think there may be enough interest to generate a prescription. It would be easy to add this to our program so please let me know your thoughts on when we should contact CDF.

107. The COO responded: "It's good to think ahead for sure. . . . [A]s long as we can set up a new fund quickly I don't think there is any rush. Maybe you can discuss with [CDF] and tell [CDF] that at some point down the road we will probably start seeing lupus prescriptions so we can hear from them how quickly it can be set up."

108. On Friday, September 2, 2011, the Reimbursement Manager wrote CDF: "We are moving into a new area, lupus, and we would like to set up a public [Medicare] fund for this disease state. How quickly can we do this . . . ?"

109. CDF's Senior Director responded on the same day: "A public find [*sic*] takes me 24hours [*sic*] to set up. I will send over our agreement template. What is the name of the product?"

110. Mallinckrodt's Reimbursement Manager responded the same day, stating:

111. The Reimbursement Manager reported back to Mallinckrodt's COO the same day that "[CDF] can set up a copay fund for lupus with[in] 24 hours. She is going to send over a template agreement. We can have a fund established next week if you'd like."

112. The Reimbursement Manager replied to CDF via email on September 6, 2011 "let me know what we need to do in order to get this fund set up" and then again on September 12, 2011, "[c]an you help me out with this?" After further interaction with CDF, the Reimbursement Manager reported to the COO on September 20, 2011, that "[w]e are going to open a copay fund for Lupus," and said that calling it another "exacerbation" fund would be necessary to exclude other drugs from it. He wrote: "I was thinking of calling it something like 'Acute Exacerbation of Lupus Fund' so we don't open ourselves up to other drugs being used for maintenance therapy." He continued: "[CDF] said if we established the fund for exacerbations, Acthar patients that may be prescribed Acthar for maintenance could still get coverage."

113. The COO responded: "I am OK using the name you proposed but I would not want us to be limited in terms of what patients can enroll, given our very broad [FDA] label." He continued that the "only real maintenance drug is Benlysta" and that the fund should be named in such a way to "capture most of the use of Acthar but exclude most Benlysta use." "For example," the COO wrote, "our current MS fund is titled 'MS acute exacerbations', which allows Actahr [*sic*] patients to get covered but excludes Avonex, Copaxone, etc. patients."

114. CDF then prepared a contract for Mallinckrodt to establish the "Lupus Exacerbation" fund, and Mallinckrodt's COO signed it on October 31, 2011.

115. The Lupus Exacerbation Fund agreement contained false statements similar to those in the MS Exacerbation Fund agreement. It falsely stated that the fund would pay for "any

medically appropriate therapy," and that the fund's eligibility criteria were developed without any donor's "input." It also falsely stated that CDF already had such a fund.

116. Two days later, on November 2, 2011, Mallinckrodt wired an initial $25,000 payment to CDF. The fund then opened.

117. From this point through 2014, the Lupus Exacerbation fund paid the Medicare copays of Acthar but no other drug.

118. Again, as it did with the MS Acute Exacerbation fund, Mallinckrodt knew a significant portion of its Acthar referrals for lupus were for longer-term, non-acute treatment. In fact, because "maintenance" treatment for Lupus was on-label, Mallinckrodt planned to market Acthar for this use.

119. According to Mallinckrodt, the Lupus "pulse maintenance opportunity is similar to the pulse-maintenance approach in MS" and posed a "[l]arge per patient revenue opportunity" for the Company. As of August 2012, Mallinckrodt estimated that 40 percent of its "[t]arget [p]opulation" for Lupus would be maintenance patients and, by November 2012, observed that while the "[e]xpected dosage for each [Lupus] flare is 1.5 vials," the "[v]ials per script [would] gradually increase[] to account for maintenance therapy[.]"

120. Mallinckrodt sent longer-term patients to the so-called Lupus "exacerbation" fund via ASAP, as it did with MS. The fund sometimes paid for continuous Acthar refills that went on for months or years.

C. The RA "Exacerbation" Fund

121. In the summer of 2012, Mallinckrodt started marketing Acthar as a treatment for Rheumatoid Arthritis and soon determined that it needed another Acthar-only fund at CDF to pay the Medicare copays of these patients, too. On September 13, 2012, just three hours after

receiving questions from ASAP about whether copay subsidies would be available for Acthar RA referrals, Mallinckrodt's Reimbursement Manager emailed CDF's Senior Director and a CDF Quality Analyst asking them to schedule a call with him, the COO, and the Commercial VP to "to discuss setting up a public fund for RA," and noting that "[w]e'd like work with you on what to call this[.]" CDF scheduled the call for 10:30 AM the next morning, September 14, 2012.

122. Even though the fund had not opened yet, CDF started planning for Mallinckrodt's referrals to it. Shortly after noon on September 14, 2012, the CDF Quality Analyst wrote to all CDF call center employees (who received referrals over the phone from ASAP) that: "All, [i]f we have any referrals/requests for assistance with RA and the patient is being treated with Acthar, please get all of the patient's information and notate their account. . . . Advise the patient that we will contact them back in regards to the assistance. Then email me and the [Senior Director] with the ID number for the patient. Under no circumstances should you say or indicate that we do not have a fund open at this time . . . I need each of you to email me back regarding this communication indicating that you have read and understood the above message."

123. Meanwhile, Mallinckrodt prepared for the fund's opening on its end. On September 15, 2012, the BioSolutia Consultant reported back to ASAP that he expected the fund to be opened shortly: "As described by [the Reimbursement Manager] during yesterday's status call, . . . in about a week [he] expects to have a fund established to be able to also provide [copay subsidies] for patients with [Medicare Part D]" for RA referrals.

124. Mallinckrodt was now accumulating Acthar RA referrals where the sale could not be completed without copay assistance. On September 18, 2012, the BioSolutia Consultant

emailed Mallinckrodt's Reimbursement Manager, "[a]ny new info on Med-D RA fund? Cases holding." The Reimbursement Manager replied "No word yet."

125. The same day, Mallinckrodt's Reimbursement Manager wrote to CDF: "Sorry to be a pest but I'm at a meeting with [the COO] and [the Commercial VP] and they are constantly asking me if I've heard any information from you guys." CDF had responded that CDF needed to confer with its own counsel before proceeding further. On September 21, 2012, the Reimbursement Manager wrote again: "[The COO] and [the Commercial VP] are getting really anxious about this fund because we have several patients that are in need of funding and waiting for drug. Can you please update me?" Later that day CDF agreed to "open the fund under the category of Exacerbation of Rheumatoid Arthritis[.]"

126. Mallinckrodt's Reimbursement Manager emailed Company rheumatology sales force personnel several hours later that "I am happy to announce that we just established a fund at CDF for RA patients. The fund is titled 'Exacerbation of Rheumatoid Arthritis' . . . [T]his is a great addition to our offerings. What this means is that we can now offer RA patients with [Medicare Part D] copay assistance." From this point forward, the RA Exacerbation Fund paid the Medicare copays of Acthar but no other drug.

127. Based on reports and tracking it received on refill patterns from ASAP, Mallinckrodt knew that some of the Acthar referrals it made to CDF's RA "Exacerbation" fund were actually for long-term use. As with MS and Lupus, Mallinckrodt sent these patients to the RA "Exacerbation" fund via ASAP and, through it, paid copay subsidies for sometimes months' or years' worth of Acthar refills.

## III. MALLINCKRODT SENT MEDICARE PATIENTS TO THE FUNDS IT CREATED AT CDF TO RECEIVE ACTHAR COPAY SUBSIDIES

128. Shortly after establishing the MS Acute Exacerbation fund, and continually as it established the Lupus and RA Exacerbation funds, Mallinckrodt directed ASAP to send to CDF any Medicare patient who needed a copay subsidy to buy Acthar.

129. On July 15, 2010, the same day he sent the executed MS Acute Exacerbation fund contract to CDF, the Mallinckrodt COO wrote to the BioSolutia Consultant and the Reimbursement Manager to "ensure that gets implemented at the hub" (*i.e.*, ASAP). Within a month, this was complete. On August 13, 2010, the Reimbursement Manager wrote to Mallinckrodt's COO that "[The BioSolutia Consultant] and I have instructed ASAP to send all copay patients to CDF and they are being handled without delay."

130. Mallinckrodt initially directed ASAP to proactively offer copay assistance to any patient with Acthar copays in excess of $200 but later reduced that threshold to $150 to reduce the likelihood of Mallinckrodt "losing some referrals" absent an "automatic offering" of Acthar copay assistance.

131. As the Reimbursement Manager announced to the sales force on June 25, 2012:

> Based on feedback from you and your managers, we have evaluated our current business rule of automatically offering copay assistance. Our current threshold for ASAP to proactively ask the patient if they need assistance with their copay is $200 and **several of you suggested that we lower that amount because there are concerns about losing some referrals where the patient does not receive an automatic offering of copay assistance. Effective today, ASAP will begin proactively offering copay assistance to all patients with copays greater than $150.** Keep in mind that patients needing assistance with smaller copay amounts will still be referred to CDF. We will monitor how this change impacts cases over the next several months and evaluate if a further reduction is necessary.

(Emphasis added).

132. Through this automated process that Mallinckrodt coordinated, Mallinckrodt filled the funds at CDF with patients the Company sent there itself. Mallinckrodt's ASAP program referred over 98 percent of the patients who received copay subsidies from the MS, Lupus, or RA "Exacerbation" funds at CDF.

133. Mallinckrodt also knew that virtually all of the patients it sent to CDF would receive copay subsidies for Acthar. As early as August 2010, Mallinckrodt's Reimbursement Manager assured a regional sales manager that: "Almost every patient that requests assistance will be approved, with the exception of very wealthy families." Mallinckrodt maintained this expectation of virtually guaranteed copay subsidies throughout the time period, as CDF confirmed for Mallinckrodt that it was approving almost every patient the Company sent there.

## IV. MALLINCKRODT EXCLUDED MEDICARE PATIENTS FROM ITS FREE DRUG PROGRAM

134. During the same time period that Mallinckrodt sent Acthar patients to CDF to receive Medicare copay subsidies, the Company also retained NORD to operate a "Patient Assistance Program" ("PAP") that offered free Acthar to patients who met certain financial criteria and could not afford the drug's high price. ASAP also sent certain patients to NORD for that purpose.

135. But Mallinckrodt intentionally did not send Acthar patients with Medicare or other insurance coverage for the drug to the NORD PAP. Instead, Mallinckrodt sent those patients to CDF where they received copay subsidies to cover their costs and triggered insurance reimbursement for Acthar. Mallinckrodt also required patients to appeal insurance coverage denials of Acthar before referring them to the PAP. According to Mallinckrodt, patients "[m]ust exhaust appeal options after denials" and "[i]f we **exhaust** appeal options, patient will be referred to [PAP]." (Emphasis in original.)"

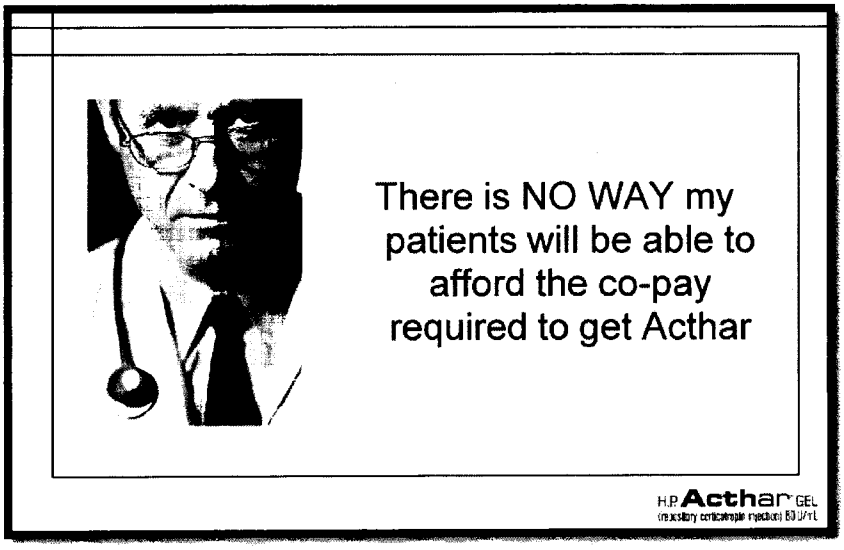
136. In other words, whenever possible, Mallinckrodt sought to cause Medicare claims to be submitted for Acthar so that Mallinckrodt could get paid from a sale of the drug as opposed to giving it away for free through the NORD PAP. As the BioSolutia Consultant wrote to the Reimbursement Manager on November 17, 2010: "We're in the 'sell more Acthar now business' not the give more Acthar now."

## V. MEANWHILE, MALLINCKRODT MARKETED ACTHAR AS FREE TO DOCTORS AND THEIR PATIENTS

137. Mallinckrodt marketed guaranteed copay assistance to physicians and patients as a way to neutralize concerns about the price and to induce sales and Medicare reimbursement. This began immediately after establishing the MS Acute Exacerbation Fund at CDF and continued throughout the relevant time period.

138. For example, on August 4, 2010, the Reimbursement Manager provided all regional sales managers with "talking points to use with [their] teams" on how to sell Acthar using copay assistance at CDF. He wrote that the "[m]essaging to [doctors]" should be "we offer copay assistance" and that "patients that need assistance will [ ] get approved over the phone in most cases."

139. The same month, Mallinckrodt developed talking points and trainings for the sales force to evade objections to Acthar's high price and to sell Acthar using the promise of copay subsidies. The very first talking point read: "DO NOT APOLOGIZE FOR THE PRICE." The training directed sales representatives to "[r]eview [the] co-pay coverage program" with prescribers who expressed concern about the drug's price. A set of Mallinckrodt training slides visualized anticipated objections about high copays this way:




The slides instructed the sales force to address this objection by telling doctors that, **"[i]f a patient is unable to afford their co-pay, we offer an excellent co-pay coverage program" and "when co-pay is covered (in virtually all cases) it is for 100% of the co-pay."** (Emphasis added). According to the training, "the process is fast."

140. Mallinckrodt's Reimbursement Manager also emailed all sales representatives on October 19, 2010 with a "Tip of the Week" message to emphasize the importance of marketing Acthar as zero-cost to most patients. He stated: "Please be sure that your offices are aware of our Copay Assistance Program. It is important that the MD's and nurses are aware of this program and understand it enough to explain it to their patients."

141. Mallinckrodt meanwhile conducted extensive market research to confirm that these methods were effective. For example, Mallinckrodt commissioned a market study of neurologists to examine Mallinckrodt's concern that "as a consequence of the price increase and the loss of goodwill physicians may be switching away from Acthar to alternative therapies." The study reported as a "bottom line" that there is "pricing angst in MS" and that many MS physicians "consider [Acthar] to have a very poor value in terms of efficacy vs cost." It also

reported that potentially high patient copays for Acthar concerned MS physicians: of the MS physicians surveyed, 25 percent reported not prescribing Acthar in the last twelve months because the "patient copay is too high" after the price increase.

142. Mallinckrodt internalized the study's findings in its sales plan for Acthar. Addressing the question of "What Will Increase Prescribing?", Mallinckrodt's plan noted that "copay support" is "important" because "cost to the patients is a key concern."

143. Mallinckrodt took steps to ensure that the sales force executed the Company's sales strategy of marketing Acthar as free due to virtually guaranteed copay subsidies via CDF. For example, on June 9, 2011, an Acthar Product Manager at corporate headquarters (the "Product Manager") sent an email to the sales force managers asking that they survey the sales representatives in each of their respective regions and ask three questions: 1) whether the representatives messaged co-pay assistance; 2) what percentage of the time did they discuss co-pay assistance; and 3) "how do [they] message co-pay assistance for Acthar?" Their answers, reported back through the sales managers to the Product Manager and the Reimbursement Manager, confirmed that the sales force had been using copay assistance for Acthar as a "selling tool," as the Company intended. The sales representatives' responses included:

- "I.use.co.pay [*sic*] assistance program as a selling tool."
- "Call it co-pay coverage. If your [patient] hits donut hole in Med D and has huge co-pay or has a $50 co-pay that they can't afford, [Mallinckrodt] will cover it for them."
- "I make sure that the nurse presents the co-pay assistance info to the patient to prevent them from jumping to any wrong conclusions if the co-pay is high."
- "[F]or higher copays, patients can get co-pay assistance through a fund set up by [Mallinckrodt] through [CDF]."

- "99% of the time; Most every call when the cost to the patient is discussed; I discuss it more frequently when there is a pushback on the copays []; Almost every call."

- "Do not let cost be the reason why you wouldn't RX Acthar."

- "I reference co-pay assistance to physicians, ancillary staff and billing. I talk about it 100% of the time. It is part of all calls . . . [Mallinckrodt] provides co-pay assistance for patients in need covered at 100%."

- "Most every call especially when the cost to the patient is discussed. I state . . . [if] for any reason the copay is more than $200 the patient will automatically get copay assistance and will get the ACTHAR for free. I also state that if the patient expresses concern on the amount of the copay under $200 they can still qualify for copay assistance and get it for free."

- "I discuss that no co-pay amount is too small for [Mallinckrodt] to cover . . . Cost is the issue in my territory. I have to talk about the copay assistance program with my accounts."

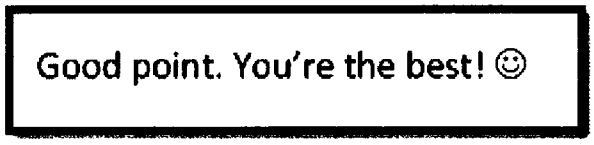
- "[Mallinckrodt] generally covers whatever insurance does not[,] so[] no concern for patient having to bear the financial burden for cost of Acthar."

- "Many of our Acthar patients do not pay a co-pay because of our extensive co-pay assistance program."

144. When one sales representative indicated that she was not clear on the details of the Acthar "bucket" Mallinckrodt established at CDF, the Mallinckrodt Product Manager tried to justify her confusion to the Reimbursement Manager, noting that, "to be fair though, I would admit I have a lot to learn about this too. Maybe we could talk about the exact details sometime so I can be a pro too." In an e-mail on June 17, 2011, the Reimbursement Manager rejected this explanation:

> No need to add "To be fair" to this email. You weren't trained like the sales force so it's not surprising that you aren't an expert in this area. **Our reps are out there selling the most expensive drug on the planet and one of them didn't know about our copay bucket for AE of MS. That's a shocker and probably makes her less effective when trying to get new MDs to write.**

(Emphasis added). The Product Manager responded:




145. Mallinckrodt's sales force continued to promote guaranteed Acthar copay subsidies via CDF in this manner, with the intent to induce Medicare Part D claims throughout the relevant time period.

## VI. MALLINCKRODT CONTINUED TO MAKE PAYMENTS TO CDF AND UNDERSTOOD THAT ITS "DONATIONS" SUBSIDIZED ACTHAR COPAYS EXCLUSIVELY

146. Mallinckrodt made continued payments to CDF to keep subsidizing Acthar copays through the MS "Acute Exacerbation," Lupus "Exacerbation" and RA "Exacerbation" funds throughout the relevant time period. Knowing that each fund covered Acthar exclusively, Mallinckrodt intended to keep these financial conduits functioning smoothly by fully funding them to subsidize the copays of all the Acthar patients Mallinckrodt sent to CDF.

147. Mallinckrodt monitored this by receiving detailed financial reports from CDF, called "Program Reports," containing information about how many patients were enrolled in the fund, how much the fund had already paid out, and how much had been allocated to enrolled patients. The reports also stated the percentage of patients approved to receive copay subsidies, the average copay amount paid by the fund, the total number of resulting drug "dispenses" (broken out by new dispenses vs. refills), and the remaining fund balance.

148. Because these funds paid Acthar copays only, all of these reported metrics were specific to Acthar. This gave Mallinckrodt the ability to monitor its fund balances and confirm the amount of future Mallinckrodt-to-CDF payments necessary to keep paying Acthar copay subsidies smoothly.

149. For example, on August 13, 2010, shortly after the MS Acute Exacerbation Fund opened, the Reimbursement Manager wrote to Mallinckrodt's COO: "I'll be receiving updated reports from [CDF] later this afternoon so I can keep an eye on the fund balances[.]" The COO replied: "Good. Let's keep a close eye on usage and we can replenish as necessary." On May 22, 2012, the Reimbursement Manager wrote to the Commercial VP: "Here is the latest funding balance at CDF. I am setting up a call with [CDF] so we can walk through these numbers to see where we stand for actual dollars. The amount of funding for patients has dramatically increased due to volume and the Med-D copay amounts during Q1."

150. Mallinckrodt also compared this information to internal information it received in reports from ASAP to check that the amounts CDF reported as necessary for future Acthar subsidies were, in fact, necessary for that purpose. The reports from ASAP included a daily "Case Review" report, via the BioSolutia Consultant, that identified: the status of each Acthar referral received; confirmation that specific patients had been referred to and accepted by CDF; and confirmation that these patients' Acthar vial(s) had been purchased and shipped as a result. The reports also identified whether referrals to CDF (and approvals by CDF) were for Medicare Part D patients.

151. This information, combined with the CDF reports, confirmed for Mallinckrodt that CDF was using Mallinckrodt's "donations" to pay the Acthar Medicare copays of the same patients Mallinckrodt sent to CDF. If there were questions about whether a request from CDF for more funding was justified, Mallinckrodt double-checked the request against this information to confirm it.

152. For example, on October 28, 2011, the Reimbursement Manager wrote the COO that CDF had informed him that it needed more funding for the MS Acute Exacerbation fund,

Lupus Exacerbation fund and the Private Fund, and that CDF had "promised me a report by next Wednesday that will show us the amount of real dollars paid out for each fund so we know exactly where we sit as the year comes to an end." The COO responded: "I assume you have reviewed the pattern of funding and utilizing of money for these funds and that this level of funding is appropriate for each, or are we waiting for [CDF's] report to do so?" The Reimbursement Manager replied: "I have been carefully watching the volume of copay assistance requests for each disease state and I reviewed the approximate fund balances with [CDF] last week. The funding requested by CDF is appropriate for each disease state and we continue to see a high demand for copay assistance for MS patients[.]" The COO replied "OK, I'll approve these and forward to accounting for payment."

153. On September 1, 2012, Mallinckrodt and CDF entered into a "Service Agreement Amendment" to their July 15, 2010 "agreement to administer a Copay Assistance Program" for Acthar (collectively, "Amendment"). The Amendment provided that Mallinckrodt would provide "bulk donations" to CDF "with the intention of funding all programs in which H.P. Acthar Gel is on formulary" and that CDF would "distribute the donations . . . as needed" internally to ensure uninterrupted copay subsidies for Acthar by each fund. From that point forward, CDF styled its "donation request" letters to Mallinckrodt as seeking money for the "H.P. Acthar Gel Programs," *i.e.*, not for a specific fund.[2] Mallinckrodt made payments on this basis through December 2013, always paying the amounts CDF requested for the "H.P. Acthar Gel Programs."

[2] Prior to this, Mallinckrodt would sometimes "roll over" funds that it had already donated to the Private Fund at CDF into the other funds paying Acthar Medicare copays, upon notice from CDF that these funds were running low.

154. In December 2013, CDF decided to close Mallinckrodt's funds but was willing to subsidize already-enrolled patients for another year if Mallinckrodt continued to make payments to CDF to do so. Mallinckrodt continued to subsidize Acthar copays using CDF through 2014 and made additional payments to the "H.P. Acthar Gel Programs" for that purpose.

155. From 2010 through 2014, Mallinckrodt made the following payments to CDF for the MS Acute Exacerbation fund, Lupus Exacerbation fund, RA Exacerbation fund, or the "H.P. Acthar Gel Programs" (including the Private Fund):

| Date | Amount |
|---|---|
| 07/21/10 | 11,000.00 |
| 07/21/10 | 117,000.00 |
| 09/17/10 | 75,000.00 |
| Total | 203,000.00 |

| Date | Amount |
|---|---|
| 01/13/11 | 150,000.00 |
| 01/13/11 | 150,000.00 |
| 04/08/11 | 150,000.00 |
| 04/08/11 | 150,000.00 |
| 05/23/11 | 150,000.00 |
| 05/23/11 | 150,000.00 |
| 07/13/11 | 150,000.00 |
| 07/13/11 | 150,000.00 |
| 08/29/11 | 150,000.00 |
| 08/30/11 | 150,000.00 |
| 11/02/11 | 150,000.00 |
| 11/02/11 | 150,000.00 |
| 11/02/11 | 25,000.00 |
| Total | 1,825,000.00 |

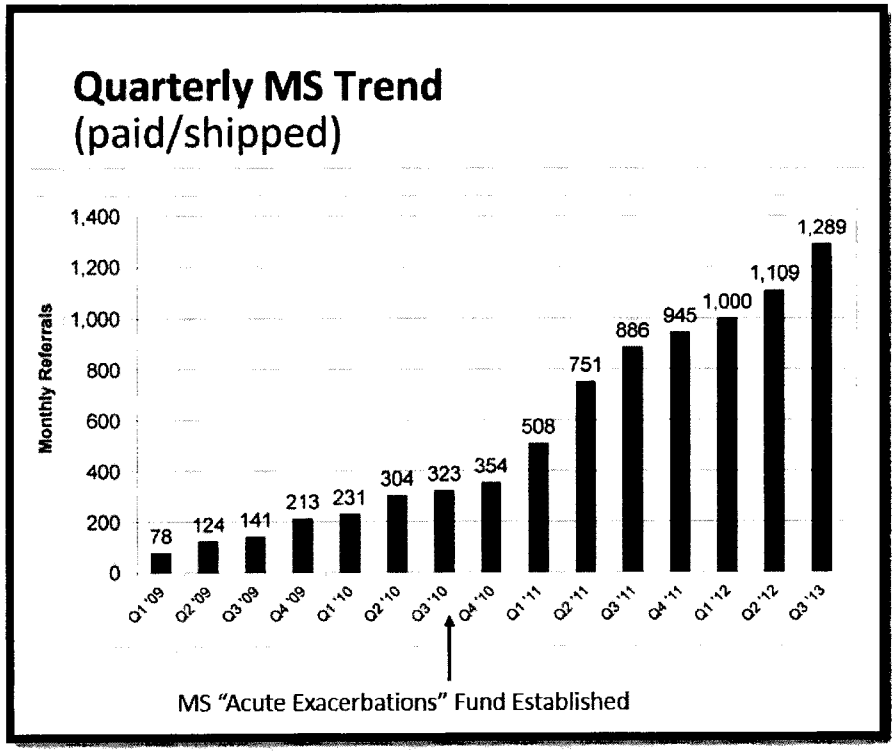
| Date | Amount |
|---|---|
| 02/03/12 | 100,000.00 |
| 02/03/12 | 100,000.00 |
| 04/06/12 | 500,000.00 |
| 06/14/12 | 1,000,000.00 |
| 07/10/12 | 800,000.00 |
| 07/24/12 | 750,000.00 |
| 08/29/12 | 850,000.00 |
| 10/10/12 | 850,000.00 |
| 11/14/12 | 850,000.00 |
| 12/14/12 | 900,000.00 |
| Total | 6,700,000.00 |

| Date | Amount |
|---|---|
| 01/18/13 | 1,200,000.00 |
| 02/25/13 | 883,000.00 |
| 04/04/13 | 1,550,000.00 |
| 04/24/13 | 341,500.00 |
| 05/14/13 | 897,000.00 |
| 06/26/13 | 500,000.00 |
| 06/27/13 | 590,500.00 |
| 07/26/13 | 1,165,000.00 |
| 10/04/13 | 957,000.00 |
| 10/07/13 | 987,300.00 |
| 10/08/13 | 200,000.00 |
| 10/25/13 | 902,000.00 |
| 12/18/13 | 1,354,000.00 |
| Total | 11,527,300.00 |

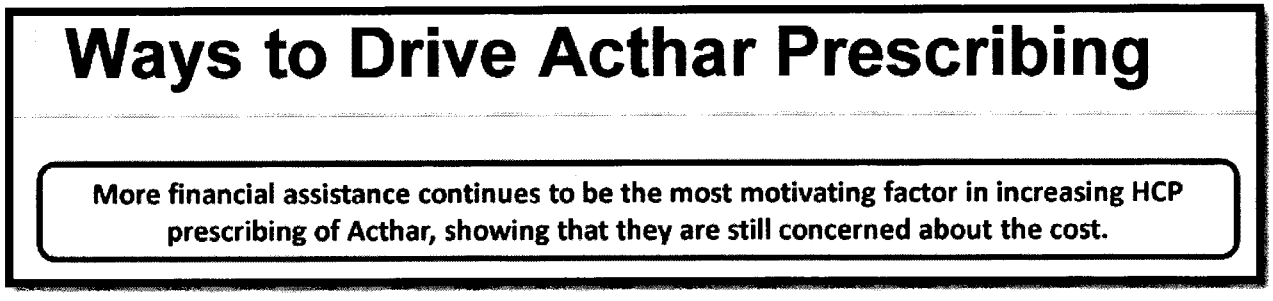
| Date | Amount |
|---|---|
| 01/10/14 | 1,004,600.00 |
| 02/11/14 | 801,100.00 |
| 03/03/14 | 367,000.00 |
| 04/01/14 | 117,500.00 |
| 05/20/14 | 360,500.00 |
| 06/13/14 | 117,000.00 |
| 08/08/14 | 232,000.00 |
| 09/11/14 | 52,000.00 |
| 10/16/14 | 52,000.00 |
| 11/14/14 | 52,000.00 |
| 12/12/14 | 52,000.00 |
| Total | 3,207,700.00 |

## VII. AS MALLINCKRODT'S SCHEME WORKED, IT INCREASED ACTHAR'S PRICE AND PROFITS

156. After Mallinckrodt established the co-pay conduit at CDF, the Company achieved significant growth in Acthar MS sales and corporate revenue. For example, as demonstrated below, Acthar MS sales nearly quadrupled between the third quarter of 2010 (when Mallinckrodt established the MS "acute exacerbation" fund, as annotated) and the third quarter of 2013.

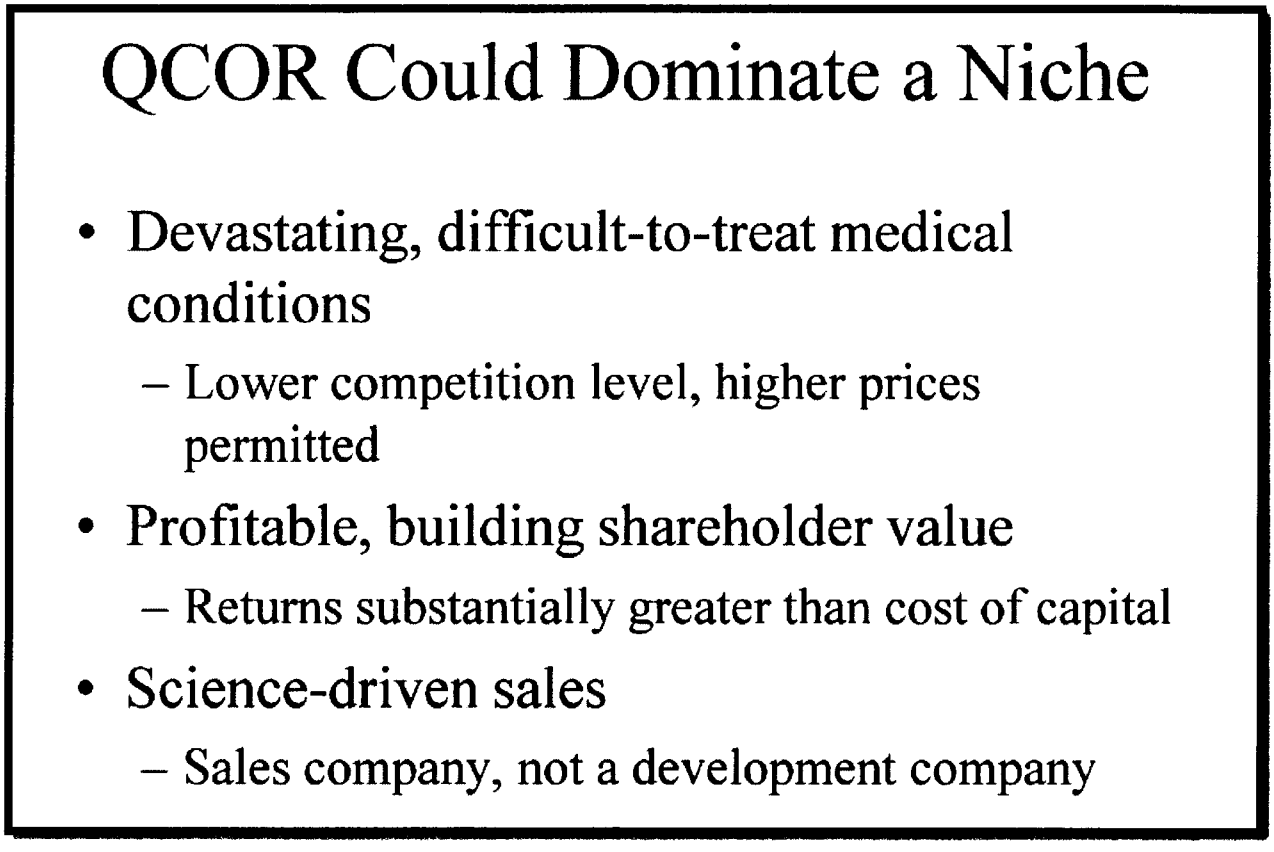



157. Mallinckrodt believed that covering Acthar copays through CDF was a key driver for these sales. In a business plan for 2013, for example, Mallinckrodt observed that "more financial assistance" was the single most significant "motivating factor" that would "increase likelihood of using Acthar" and address "concern[] about the cost" of the drug:




158. Not long after establishing the MS "acute exacerbation" fund at CDF, Mallinckrodt executed a sustained pattern of subsequent price increases. On December 4, 2010, Mallinckrodt's CEO circulated a presentation pitching that Mallinckrodt was a "sales company,

not a development company" and could position itself to "dominate" certain niche markets for other "devastating, difficult-to-treat conditions" with "higher prices":




159. Although the Company's total revenues had already increased approximately ten times over since 2006 (the year before the price increase to $23,000), from 2010 to 2014, Mallinckrodt implemented further price increases as it expanded its copay conduit scheme at CDF. On January 3, 2011 Mallinckrodt raised Acthar's price to over $24,430 per vial. Under six months later, it raised the price again to over $25,600 per vial. In December 2011, it raised the price to over $27,300 per vial. In May 2012, it raised the price to over $28,680 per vial. In June 2013, it raised the price to over $30,100 per vial. In January 2014, it raised the price to over $31,600 per vial. And, in December 2014 it raised the price to over $32,200 per vial.

160. Mallinckrodt's revenue and profits increased substantially after increasing Acthar's price further. For example, the Company reported net sales of Acthar of over $761 million by the end of 2013.

## MALLINCKRODT KNOWINGLY AND WILLFULLY VIOLATED THE AKS BY PAYING ACTHAR MEDICARE COPAYS

161. Mallinckrodt knowingly and willfully violated the AKS by paying illegal Acthar copay subsidies as described above to induce prescriptions and sales of Acthar reimbursed by Medicare.

### I. MALLINCKRODT KNEW THAT THE AKS PROHIBITS THE COMPANY FROM PAYING ACTHAR MEDICARE COPAYS

162. Mallinckrodt had knowledge and understanding of the AKS and its prohibition on paying remuneration with an intent to induce purchases or referrals. Mallinckrodt also had knowledge and understanding of the False Claims Act and its prohibition on submitting, or causing to be submitted, false claims to federal health care programs, including Medicare. Mallinckrodt further knew that claims resulting from kickbacks are not payable by Medicare and that it was illegal to offer Medicare beneficiaries inducements in the form of copay subsidies. Mallinckrodt trained its employees on these laws, including the key individuals who interacted with CDF, and they understood that it would be unlawful for Mallinckrodt to pay patients' Acthar Medicare copays.

163. Mallinckrodt compliance training stated that "[c]ompliance with various laws and regulations that impact interactions with health care professionals . . . , customers, or others who may purchase, prescribe, [or] influence the use of Mallinckrodt's products" includes compliance with "Healthcare fraud & abuse; Anti-kickback statutes, [and the] False Claims Act." Regarding the "Kickback Prohibition," the training warned that "[e]mployees must never provide anything

of value (money or in-kind) as an inducement or a reward for purchasing, prescribing, using, or recommending Mallinckrodt's product(s)." Another Mallinckrodt compliance training specified that the "Anti-Kickback Laws" "prohibit payments intended to induce someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs."

164. Mallinckrodt's corporate policies also reflected Mallinckrodt's knowledge that such payments are illegal and that causing the submission of false claims to Medicare violates the False Claims Act.

165. Mallinckrodt's "Reimbursement Assistance" policy stated that:

> Under the False Claims Act, it is a violation of law for anyone to knowingly make, or cause others to make, false statements or claims to the federal government. Misuse of a diagnosis code, or any other inaccuracy submitted in any of the information submitted in a claim for reimbursement from a Federal Health Care Program could be challenged as a false claim.

166. The same policy specified that it is a violation of the AKS to offer "Reimbursement Assistance"—which includes "referrals to financial assistance programs or patient assistance programs"—to induce the use or purchase of Acthar: According to the policy, "the Anti-Kickback Statute prohibits providing Reimbursement Assistance" to someone "who is 1) involved in the provision of health care services; and 2) in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or influence the purchase or lease of, [Mallinckrodt's] products" to "induce him or her to purchase, recommend, use, or arrange for the purchase or prescription of [Mallinckrodt] products."

167. The Mallinckrodt employees interacting with CDF understood the law, as explained in these policies and trainings. These employees knew that Mallinckrodt could not legally pay Medicare copays for Acthar. For example, on June 24, 2010, the Reimbursement

Manager emailed the Commercial VP: "I don't think we can reimburse patients directly if they have a government payer (Med-D or Medicaid HMO)." Mallinckrodt's Commercial VP responded: "You are right if it's Medicare part D."

168. Mallinckrodt's employees also understood that the pharmaceutical industry in general viewed paying Medicare Part D copays as illegal under the AKS. Trade publications they circulated shared this view. For example, on February 11, 2010, the BioSolutia Consultant emailed Mallinckrodt's Reimbursement Manager an email entitled "copay articles," and attached several articles, including a January 2010 publication from "Pharma Exec" (the industry website at www.pharmaexec.com, which describes itself as offering "Commercial Insight for the C-Suite"). The publication stated that copay subsidies from manufacturers to patients "have emerged as the preferred solution to preserving market share" but that "co-pay offsets are an illegal inducement for Medicare Part D beneficiaries." The email also attached a *Wall Street Journal* Article from July 2009 entitled "Drug Makers Criticized for Co-Pay Subsidies" that stated: "Even as U.S. lawmakers seek new ways to rein in health-care spending, drug companies are quietly circumventing a proven tool for controlling prescription-drug costs: insurance co-payments." The article noted that drug companies don't pay copay subsidies for Medicare Part D patients "out of a concern" that doing so "could violate the federal anti-kickback law." The next day, The Reimbursement Manager forwarded the articles to the Commercial VP, writing "[a]ttached are some articles [the BioSolutia Consultant] pulled regarding copay subsidies. I sent you the Pharma Exec article last month so you may [have] already seen that one."

169. Nevertheless and despite knowledge that its payment of copays directly to Medicare Part D beneficiaries would violate the AKS, Mallinckrodt designed the MS, Lupus, and RA "Exacerbation" funds at CDF as conduits to accomplish the very same result.

## II. MALLINCKRODT KNEW THAT HHS-OIG WARNED DRUG COMPANIES AGAINST USING FOUNDATIONS AS CONDUITS TO PAY MEDICARE COPAYS

170. For over 20 years, HHS-OIG has been authorized by Congress to provide guidance to the health care industry to prevent fraud and abuse. *See* The Health Insurance Portability and Accountability Act ("HIPAA") of 1996, Public Law 104-191 § 201; 42 U.S.C. § 1320a-7c. To further this goal, and pursuant to this authority, HHS-OIG issues industry-wide guidance and advisory opinions about industry practices or arrangements that pose risks under anti-fraud laws such as the AKS.

171. Since at least 2005, just after Medicare Part D's enactment but prior to the first coverage year (2006), HHS-OIG has issued industry wide guidance concerning the practice of drug companies subsidizing the copays of Medicare patients.

172. Mallinckrodt knew that HHS-OIG warned drug companies against paying the Medicare copays owed for their own drugs, and against using foundations as conduits to accomplish the same result, because doing so created a risk of AKS liability.

### A. HHS-OIG Has Long Warned That Drug Companies Paying the Medicare Copays of Their Own Products Implicates The AKS And Facilitates Price Increases

173. In 2005, HHS-OIG issued industry-wide guidance advising that drug companies paying Medicare patient's Part D copays (either directly or indirectly through a manufacturer's patient assistance program) "pose a heightened risk of fraud and abuse under the [AKS]." *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, *70,624 (Nov. 22, 2005) (https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/PAPAdvisoryBlletinFinal-Final.pdf) ("2005 SAB"). In particular, HHS-OIG advised that, in its view, such subsidies would "be squarely prohibited by the [AKS], because the

manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product." 2005 SAB at 70,625. HHS-OIG further expressed the concern that this practice would present "all the usual risks of fraud and abuse associated with kickbacks" and could facilitate inflated prescription drug prices: "[w]e are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." 2005 SAB at 70,626.

174. Moreover, HHS-OIG cautioned that "[copay] subsidies can be very profitable for manufacturers," because a drug's sale price exceeds the amount of the copay subsidy. *Id.* This provides "additional incentives for abuse." *Id.*[3] HHS-OIG also cautioned that "pharmaceutical manufacturers may seek to improperly maximize these profits by creating sham 'independent' charities to operate [a Patient Assistance Program]" or "by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products[.]" 2005 SAB at 70,626.

B. HHS-OIG Has Long Warned Drug Companies Against Using Foundations As Conduits To Accomplish the Same Result

175. Since at least 2005, HHS-OIG has also warned drug companies against using third-party foundations as mere conduits to pay Medicare copays. To avoid a potential risk of AKS liability, "the independent charity [patient assistance program] must not function as a conduit for payments by the pharmaceutical manufacturer to patients." 2005 SAB at 70,627.

[3] HHS-OIG issued a supplemental special advisory bulletin in 2014 reiterating these and other concepts from the 2005 SAB. *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120, 31,122 (May 30, 2014) (https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf) ("2014 SAB") ("the ability to subsidize [copays] for their own products may encourage manufacturers to increase prices").

176. HHS-OIG has also warned drug companies against attempting to influence supposedly independent charities into creating "funds" dedicated to the drug companies' own products. HHS-OIG advised that creating "funds" defined in reference to the symptoms (or severity of symptoms) of a disease increases the risk of fraud and abuse by increasing the likelihood that drug company donors can earmark their "donations" to their drugs, and thereby create a conduit.

> [W]e are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. **For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases.** This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. **To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories, and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.**

2005 SAB at 70,627 (emphasis added).

177. HHS-OIG has also identified other indicia that may expose a drug company to potential AKS liability, such as exerting "any direct or indirect influence" over the foundation; or "solicit[ing] or receiv[ing] data from the charity that would facilitate . . . correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." 2005 SAB at 70,626.

178. In 2006, HHS-OIG issued Advisory Opinion 06-10 to CDF, which incorporated these safeguards into its terms. (Sept. 14, 2006) ("CDF Advisory Opinion") (https://www.mygooddays.org/oig/AdvOpn06-10A.pdf).

179. Mallinckrodt knew about HHS-OIG's guidance on these AKS risks. For example, the "donation agreements" Mallinckrodt signed with CDF referenced the importance of complying with "all applicable laws, statutes, rules and regulations," including "the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)" and also highlighted the "policies of the [HHS-OIG]," including the 2005 SAB. Mallinckrodt also received a copy of CDF's Advisory Opinion.

## III. MALLINCKRODT IGNORED HHS-OIG'S WARNINGS ABOUT THE TYPE OF CONDUCT THAT WOULD VIOLATE THE AKS

180. Mallinckrodt ignored these concerns and engaged in conduct that HHS-OIG specifically warned was high-risk under the AKS.

181. Mallinckrodt did not avoid influencing CDF's creation of the MS, Lupus, and RA "exacerbation" funds. Rather, Mallinckrodt insisted that CDF create each new fund for Mallinckrodt, when Mallinckrodt needed each fund to support the Company's Acthar marketing efforts.

182. Mallinckrodt also insisted that these funds be narrowly defined in reference to symptoms of each disease, rather than supporting all drugs that treat each disease, in a bid to favor Acthar over other drugs. Mallinckrodt knew that "exacerbations" of MS, Lupus, and RA were not distinct diseases, but rather were references to each diseases' symptoms and/or their severity. For example, Mallinckrodt's 2010 Acthar business plan defined "relapses of MS" as the "periodic, sudden worsening of symptoms" in MS patients and video on Mallinckrodt's website today describes MS relapses as "an exacerbation of MS symptoms." Mallinckrodt insisted on these narrower symptom funds to help make sure its drug Acthar would be covered, to the exclusion of others, even when Acthar's FDA label was broader than the fund definition.

183. Mallinckrodt also received data that allowed it to correlate its payments to these funds with the number of Acthar prescriptions those payments subsidized. This enabled

Mallinckrodt to monitor the "usage" of its payments to CDF and keep paying CDF in amounts necessary to keep subsidizing the Acthar copays of the patients it sent there via ASAP.

184. In sum, knowing that paying Acthar Medicare copays was illegal and knowing that HHS-OIG had cautioned that using a foundation as a conduit to pay them instead posed serious AKS risk, Mallinckrodt did just that so it could market the drug as "free" and have Medicare absorb the drug's ever-increasing cost.

## MALLINCKRODT CAUSED THE SUBMISSION OF MATERIALLY FALSE CLAIMS TO MEDICARE

185. Mallinckrodt's conduct caused the submission of false claims to Medicare as a result of its AKS violations.

### I. MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS UNDER MEDICARE PART D

186. Generally, after a physician writes a prescription for a Medicare Part D beneficiary, that patient can take the prescription to a pharmacy (or submit it to a mail order specialty pharmacy) to be filled.

187. When the patient submits the prescription, the Medicare copay is due from the patient to complete the purchase of the drug and have the pharmacy fill the prescription by dispensing it to the Part D beneficiary.

188. When the pharmacy dispenses drugs to that Part D beneficiary, the pharmacy submits a claim to the beneficiary's Part D Sponsor, which, in turn, submits an electronic record of the claim, called a Prescription Drug Event ("PDE"), to CMS. After dispensing the drug, the pharmacy receives reimbursement from the CMS-funded Part D Sponsor for the portion of the drug cost not paid by the Part D beneficiary at the point of sale.

189. The PDE contains many specific representations regarding this Medicare prescription drug claim, including the patient's name, service provider of the drug, the prescriber of the drug, the name of the drug, and the quantity dispensed to the patient. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

190. Generating and submitting PDE claims data is necessary for CMS to administer the Part D program and make payments to Part D Plan Sponsors to reimburse them for qualified drug coverage that they provide to Medicare beneficiaries. Generating and submitting PDE data is a condition of payment for CMS's provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322.

191. CMS pays Part D Plan Sponsors based upon these PDEs in various ways. For example, CMS gives each Part D sponsor advance monthly payments to cover, among other things, the Part D Plan Sponsor's direct CMS subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor) and estimated reinsurance subsidies (to account for CMS's anticipated 80 percent subsidy of the "catastrophic coverage" costs that will be incurred for all enrollees). *See id.* §§ 423.315, 423.329. At the end of the payment year, CMS then reconciles the advance payments paid to each Part D Sponsor with the actual costs the sponsor has incurred, as documented by PDE data. In this reconciliation process, CMS uses the PDE claims data submitted by the Part D Sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D that year. In the case of the federal government's 80 percent reinsurance subsidy for catastrophic costs, for example, if CMS determines that it underpaid the sponsor, it will make up

the entire difference.[4] The payments made by CMS to the Part D sponsor — which in turn fund the provision of prescription drugs provided to beneficiaries at each drug dispensing event — come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

192. Part D Plan Sponsors must comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, et seq.), and the anti-kickback statute (§ 1127B(b)) of the Act)." 42 C.F.R. § 423.505(h)(1). Any "downstream" or "related" entities that Part D Plans subcontract with (including pharmacies dispensing medication) must also comply with these, and any other, contractual obligations of the Part D Plan, *see* 42 C.F.R. § 423.505(i)(3)(iii), and separately comply with all applicable federal laws, regulations, and CMS instructions. *See id.* § 423.505(i)(3)(iv).

193. CMS regulations require Part D Plan Sponsors and related "downstream" entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the health care products or services reflected therein. *Id.* § 423.505(k).

## II. THE VIOLATIONS BY MALLINCKRODT WERE MATERIAL TO THE PAYMENT DECISION

194. Compliance with the AKS is a material condition of payment by Medicare.

[4] CMS also uses PDE data to determine risk-sharing amounts owed by CMS to the plan or (if a plan significantly overestimated its non-catastrophic costs in its bid) owed by the plan to CMS. These risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. *See* 42 C.F.R. § 423.336.

195. The centrality of the AKS to the claims payment decision is demonstrated by the fact that Congress has determined that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

196. Entities submitting claims to Medicare are subject to mandatory exclusion from Medicare by HHS-OIG if criminally convicted of an AKS violation, *see, e.g.*, 42 U.S.C. § 1320a–7(a)(1), and subject to permissive exclusion if HHS-OIG determines that the provider "has committed an act" described in the AKS, 42 U.S.C. § 1320a–7(b)(7).

197. The AKS is a criminal statute specifically designed to preventing fraud on federal healthcare programs such as Medicare and prevent excessive costs to the Medicare program resulting from all forms of illegal inducements.

198. HHS-OIG has made clear that compliance with the AKS is material. It has also specifically provided guidance on its views of the risks inherent in drug companies paying copay subsidies to induce purchases of (and Medicare reimbursement for) their own drugs as potentially implicating the AKS, whether done directly or indirectly through a foundation. In particular, HHS-OIG has warned that drug company copay subsidies present "all the usual risks of fraud and abuse associated with kickbacks." HHS-OIG has voiced repeated concern that these subsidies eliminate a "market safeguard against inflated [drug] prices" and expose the Medicare program to higher costs as a result. HHS-OIG has elaborated at length on the types of safeguards that may be put in place to avoid the risk of an AKS violation.

199. The United States regularly enforces the AKS and pursues FCA liability based on underlying violations of the AKS. In particular, it has pursued matters against drug companies like Mallinckrodt for conduct like that alleged here.[5]

200. The conduct by Mallinckrodt undermined the core concerns of the AKS — in particular, preventing excessive costs to Medicare resulting from illegal copay subsidies that facilitate high drug costs and push the financial burden of those costs to Medicare and the American taxpayer.

201. Mallinckrodt's conduct was sustained and systemic. It lasted over multiple years and involved thousands of claims submitted to Medicare. After a first successful attempt to create and use a funds for its own ends of subsidizing copays for Acthar patients, the course of conduct was repeated twice more for other funds also designed to enrich Mallinckrodt at the

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[5] *Drug Maker United Therapeutics Agrees to Pay $210 Million to Resolve False Claims Act Liability for Paying Kickbacks* (December 20, 2017) (https://www.justice.gov/opa/pr/drug-maker-united-therapeutics-agrees-pay-210-million-resolve-false-claims-act-liability)

*Drug Maker Pfizer Agrees to Pay $23.85 Million to Resolve False Claims Act Liability for Paying Kickbacks* (May 24, 2018) (https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks)

*Drug Maker Actelion Agrees to Pay $360 Million to Resolve False Claims Act Liability for Paying Kickbacks* (December 6, 2018) (https://www.justice.gov/opa/pr/drug-maker-actelion-agrees-pay-360-million-resolve-false-claims-act-liability-paying
*Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations* (April 4, 2019) (https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid)

*Two Pharmaceutical Companies Agree to Pay a Total of Nearly $125 Million to Resolve Allegations That They Paid Kickbacks Through Copay Assistance Foundations* (April 25, 2019) (https://www.justice.gov/opa/pr/two-pharmaceutical-companies-agree-pay-total-nearly-125-million-resolve-allegations-they-paid)

expense of the Medicare program. The kickbacks at issue here were for millions of dollars in total and were not insignificant.

202. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is an express condition of payment under the Medicare Part D Program.

203. The submission of PDEs is essential to the functioning of the Part D Program, the singular purpose of which is to provide coverage for drug products for the Medicare population. The accuracy of the information contained in each PDE for each patient determines how much payment will be made by Part D for that particular prescription.

204. The scheme alleged here resulted in thousands of PDEs being submitted to Part D over a period of multiple years.

## III. SAMPLE FALSE ACTHAR CLAIMS

205. Through the scheme described above, Mallinckrodt provided illegal copay subsidies for over 2,600 Acthar prescriptions to induce Medicare-reimbursed purchases of the drug, resulting in millions of dollars of false claims to Medicare during the relevant time period.

206. Throughout the time period where Mallinckrodt used CDF as a conduit to pay these illegal Acthar copay subsidies, patients used these subsidies at pharmacies to purchase Acthar prescriptions, and the pharmacies submitted claims to Medicare Part D sponsors seeking Medicare reimbursement for those prescriptions. These false claims are documented in PDE data. Moreover, Part D Plan Sponsors, in turn, submitted these false PDE data to CMS as the basis for payments from the federal government based upon the expenses incurred for these illegally subsidized Acthar prescriptions.

207. Prescription Drug Event data attached as Exhibits 1 and 2 demonstrate representative examples of false claims for Acthar prescriptions that were the subject of Mallinckrodt's illegal copay subsidies and reimbursed by Medicare. Each line item on these exhibits represents a distinct Prescription Drug Event reflecting a false Medicare claim for Acthar (*i.e.* a Medicare-reimbursed purchase of Acthar by a Medicare beneficiary to fill an Acthar prescription using a copay subsidy). In each instance, the drug is identified as Acthar by both its "National Drug Code" ("NDC Code") and its common name (in the "NDC Code Description") from the PDE data. In each line item, the PDE data also shows the Medicare Part D Beneficiary who received the drug, reported here in the "Bene Name" field (using a de-identified value for purposes of this exhibit).

208. In each line item, the "Date From Claim" column represents the date of service for the Medicare claim, *i.e.*, when the beneficiary purchased the Medicare-covered Acthar prescription from a pharmacy using the copay subsidy, as reported in the PDE data. The pharmacy then dispensed the units of Acthar reported in the Units Quantity Dispensed ("Units Quan Disp") column of the PDE data to the beneficiary. Acthar "units" are measured in milliliters and Acthar is sold in 5 milliliter vials. Accordingly, each multiple of 5 reported in this column represents one vial of Acthar dispensed for that claim.

209. For each line item, the "Date Processed" column represents the date Medicare processed and paid its share of the claim according to the PDE data The reported Medicare cost of the prescription is reflected in the following PDE data fields: Amount Below Out-Of-Pocket Threshold ("Amt Below OOPT") and Amount Above Out-Of-Pocket Threshold ("Amt Above OOPT"). AMT Below OOPT refers to total costs for that prescription considered to be below the "catastrophic coverage" threshold for that benefit year. AMT Above OOPT represents the

portion of the drug cost considered to be in the "catastrophic coverage" benefit phase, and subject to the Medicare Part D reinsurance subsidy.

210. For each line item, the PDE data field "Pharm ID" represents a code corresponding to the pharmacy that dispensed the prescription, and the PDE data field "Presc ID" represents a code corresponding to the referring physician for the prescription (both reported using a de-identified value for purposes of this exhibit).

211. Exhibit 1 reflects 79 representative example false claims for Acthar prescriptions that Medicare reimbursed on behalf Patients AA, AB, and AC, who Mallinckrodt sent (via ASAP) to the MS Acute Exacerbation, Lupus Exacerbation, and RA Exacerbation funds, respectively, to receive Mallinckrodt's Acthar copay subsidies.

212. Exhibit 2 reflects an additional 42 representative example false claims for Acthar prescriptions that Medicare reimbursed on behalf of the indicated patients residing in this judicial district, all of whom Mallinckrodt sent to CDF to receive Mallinckrodt's Acthar copay subsidies.

213. All 121 of these sample false claims were submitted to Medicare for reimbursement and made the specific representations for each prescription described above, including: the identity of the beneficiary, drug, pharmacy and referring physician; the Medicare claim's date of service and date Medicare processed the claim; the Medicare drug cost above and below the "out-of-pocket" threshold for each prescription; and the units of Acthar dispensed to the beneficiary for each prescription.

214. Exhibits 3 and 4 show the illegal copay subsidy amounts paid by Mallinckrodt for each sample false claim identified in Exhibits 1 and 2, respectively. Mallinckrodt paid, via CDF, the copay subsidy amounts reflected in the "Acthar Copay Subsidy Amount Paid For Claim" column (through the fund indicated by the "Fund" column) for each claim referenced in the

"Corresponding Sample False Claim No." column, to induce each Medicare reimbursed-purchase of Acthar. These payments occurred on the same date as the "Date From Claim" field reported in the PDE data for each claim and were paid to the same Medicare beneficiary reported on each claim.

215. These copay subsidy amounts (and the funds through which Mallinckrodt paid them) show each illegal copay subsidy paid for each claim based upon CDF records.

216. The claims did not disclose that the patient received illegal remuneration to induce the purchase of the drug in violation of the AKS.

**THE ACTHAR CLAIMS ALLEGED HERE ARE FALSE CLAIMS**

217. Mallinckrodt knowingly and willfully paid remuneration to Medicare patients to induce the patients to purchase Acthar by providing them with financial subsidies to satisfy the copayment obligations necessary to buy the drug.

218. Mallinckrodt knowingly caused the submission of false claims for reimbursement to Medicare in each instance in which it provided a patient with a copay subsidy through CDF for Acthar.

219. The claims are per se false or fraudulent as a matter of law. 42 U.S.C. § 1320a-7b(g).

220. The claims are also false because the PDE data and the specific representations therein fail to disclose a violation of a requirement material to the agency's payment decision, namely the AKS.

221. The PDE data was not true, accurate, and complete because it did not disclose a violation of the AKS. The PDE data for each claim was a false record that Mallinckrodt caused to be used to pay the false claims alleged herein.

222. The representations of compliance with the AKS made by the Part D Sponsor and downstream entities were false because the claims resulted from an illegal kickback. The representations were false records that Mallinckrodt caused to be used to pay the false claims alleged herein.

**COUNT I**
**(False Claims Act: Presentation of False Claims)**
**(31 U.S.C. § 3729(a)(1)(A)**

223. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

224. By virtue of the acts described above, Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for Acthar that were tainted by illegal kickbacks.

225. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of the Defendant's conduct.

226. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false or fraudulent claim.

**COUNT II**
**(False Claims Act: False Records Material To A False or Fraudulent Claim)**
**(31 U.S.C. § 3729(a)(1)(B)**

227. The United States re-alleges and incorporates by reference all paragraphs of this complaint set out above as if fully set forth herein.

228. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements, namely, false claims, false statements in PDEs, and false statements about compliance with the AKS, all of which were material to false or fraudulent claims that were submitted to the United States and paid and approved by the Medicare program for Acthar that were tainted by illegal kickbacks, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

229. Payment of the false or fraudulent claims was a reasonable and foreseeable consequence of the Defendants' statements and actions.

230. By reason of the false or fraudulent records or statements, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false record or statement.

## PRAYER FOR RELIEF

WHEREFORE, plaintiff, the United States, requests that judgment be entered in its favor as follows:

I. On Count I under the False Claims Act against Defendant, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

II. On Count II under the False Claims Act against Defendant, for the amount of the United States' damages to be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and proper.

III. All other and further relief as the Court may deems just and proper.

The United States hereby demands a jury trial on all claims alleged herein.

Dated: June 4, 2019

Respectfully submitted,

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# EXHIBIT 1

| Sample False Claim No. | NDC Code | NDC Code Description | Bene Name | Date From Claim | Units Quan Disp | Date Processed | Amt Above OOPT | Amt Below OOPT | Pharm ID | Presc ID |
|---|---|---|---|---|---|---|---|---|---|---|
| 1 | 63004773101 | ACTHAR HP | AA | 08/09/2012 | 5 | 09/05/2012 | $ 31,287.17 | $ - | Pharmacy 4 | MD 02 |
| 2 | 63004773101 | ACTHAR HP | AA | 10/03/2012 | 5 | 10/10/2012 | $ 31,287.17 | $ - | Pharmacy 4 | MD 05 |
| 3 | 63004773101 | ACTHAR HP | AA | 10/19/2012 | 5 | 10/23/2012 | $ 31,287.17 | $ - | Pharmacy 4 | MD 05 |
| 4 | 63004773101 | ACTHAR HP | AA | 11/13/2012 | 5 | 11/21/2012 | $ 31,287.17 | $ - | Pharmacy 4 | MD 05 |
| 5 | 63004773101 | ACTHAR HP | AA | 11/23/2012 | 5 | 12/10/2012 | $ 31,287.17 | $ - | Pharmacy 4 | MD 05 |
| 6 | 63004773101 | ACTHAR HP | AA | 12/28/2012 | 5 | 01/26/2013 | $ 31,287.17 | $ - | Pharmacy 1 | MD 02 |
| 7 | 63004871001 | H.P. ACTHAR | AA | 01/30/2013 | 5 | 09/16/2013 | $ 29,288.91 | $ 1,998.26 | Pharmacy 4 | MD 02 |
| 8 | 63004871001 | H.P. ACTHAR | AA | 02/26/2013 | 5 | 03/08/2013 | $ 31,287.17 | $ - | Pharmacy 1 | MD 02 |
| 9 | 63004871001 | H.P. ACTHAR | AA | 03/22/2013 | 5 | 04/26/2013 | $ 31,287.17 | $ - | Pharmacy 4 | MD 01 |
| 10 | 63004871001 | H.P. ACTHAR | AA | 04/26/2013 | 5 | 05/15/2013 | $ 31,287.17 | $ - | Pharmacy 1 | MD 02 |
| 11 | 63004871001 | H.P. ACTHAR | AA | 05/14/2013 | 5 | 09/16/2013 | $ 31,287.17 | $ - | Pharmacy 4 | MD 02 |
| 12 | 63004871001 | H.P. ACTHAR | AA | 06/14/2013 | 5 | 06/21/2013 | $ 31,537.14 | $ - | Pharmacy 1 | MD 01 |
| 13 | 63004871001 | H.P. ACTHAR | AA | 06/28/2013 | 10 | 11/12/2013 | $ 63,072.78 | $ - | Pharmacy 4 | MD 02 |
| 14 | 63004871001 | H.P. ACTHAR | AA | 07/29/2013 | 5 | 11/12/2013 | $ 31,537.14 | $ - | Pharmacy 4 | MD 01 |
| 15 | 63004871001 | H.P. ACTHAR | AA | 08/12/2013 | 5 | 08/23/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 01 |
| 16 | 63004871001 | H.P. ACTHAR | AA | 09/04/2013 | 5 | 09/16/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 01 |
| 17 | 63004871001 | H.P. ACTHAR | AA | 09/23/2013 | 5 | 10/01/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 01 |
| 18 | 63004871001 | H.P. ACTHAR | AA | 10/21/2013 | 5 | 11/12/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 02 |
| 19 | 63004871001 | H.P. ACTHAR | AA | 10/29/2013 | 5 | 11/12/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 02 |
| 20 | 63004871001 | H.P. ACTHAR | AA | 11/04/2013 | 5 | 11/12/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 02 |
| 21 | 63004871001 | H.P. ACTHAR | AA | 11/12/2013 | 5 | 11/22/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 02 |
| 22 | 63004871001 | H.P. ACTHAR | AA | 12/02/2013 | 5 | 12/09/2013 | $ 31,175.70 | $ - | Pharmacy 3 | MD 02 |
| 23 | 63004871001 | H.P. ACTHAR | AB | 09/12/2013 | 5 | 09/23/2013 | $ 26,024.31 | $ 4,848.69 | Pharmacy 2 | MD 04 |
| 24 | 63004871001 | H.P. ACTHAR | AB | 09/30/2013 | 5 | 10/21/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 25 | 63004871001 | H.P. ACTHAR | AB | 10/17/2013 | 5 | 11/05/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 26 | 63004871001 | H.P. ACTHAR | AB | 11/11/2013 | 5 | 11/21/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 27 | 63004871001 | H.P. ACTHAR | AB | 11/25/2013 | 5 | 12/05/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 28 | 63004871001 | H.P. ACTHAR | AB | 12/10/2013 | 5 | 12/23/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 29 | 63004871001 | H.P. ACTHAR | AB | 12/30/2013 | 5 | 01/06/2014 | $ 30,873.00 | $ - | Pharmacy 2 | MD 04 |
| 30 | 63004871001 | H.P. ACTHAR | AB | 01/16/2014 | 5 | 01/23/2014 | $ 23,750.93 | $ 7,122.07 | Pharmacy 2 | MD 04 |
| 31 | 63004871001 | H.P. ACTHAR | AB | 02/04/2014 | 5 | 09/17/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 32 | 63004871001 | H.P. ACTHAR | AB | 02/25/2014 | 5 | 09/17/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 33 | 63004871001 | H.P. ACTHAR | AB | 03/18/2014 | 5 | 09/17/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 34 | 63004871001 | H.P. ACTHAR | AB | 04/03/2014 | 5 | 09/17/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 35 | 63004871001 | H.P. ACTHAR | AB | 04/23/2014 | 5 | 09/17/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 36 | 63004871001 | H.P. ACTHAR | AB | 05/06/2014 | 5 | 05/22/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 37 | 63004871001 | H.P. ACTHAR | AB | 05/20/2014 | 5 | 06/07/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 38 | 63004871001 | H.P. ACTHAR | AB | 06/04/2014 | 5 | 06/23/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 39 | 63004871001 | H.P. ACTHAR | AB | 06/26/2014 | 5 | 07/23/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 40 | 63004871001 | H.P. ACTHAR | AB | 07/16/2014 | 5 | 07/31/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 41 | 63004871001 | H.P. ACTHAR | AB | 07/31/2014 | 5 | 08/18/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 42 | 63004871001 | H.P. ACTHAR | AB | 08/18/2014 | 5 | 10/09/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 43 | 63004871001 | H.P. ACTHAR | AB | 09/04/2014 | 5 | 10/14/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 44 | 63004871001 | H.P. ACTHAR | AB | 09/25/2014 | 5 | 10/14/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 45 | 63004871001 | H.P. ACTHAR | AB | 10/20/2014 | 5 | 11/18/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 46 | 63004871001 | H.P. ACTHAR | AB | 11/13/2014 | 5 | 12/02/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 47 | 63004871001 | H.P. ACTHAR | AB | 12/04/2014 | 5 | 12/23/2014 | $ 32,416.65 | $ - | Pharmacy 2 | MD 04 |
| 48 | 63004871001 | H.P. ACTHAR | AB | 12/22/2014 | 5 | 01/07/2015 | $ 33,066.50 | $ - | Pharmacy 2 | MD 04 |
| 49 | 63004871001 | H.P. ACTHAR | AC | 07/01/2013 | 5 | 07/27/2013 | $ 27,826.09 | $ 3,757.10 | Pharmacy 3 | MD 03 |
| 50 | 63004871001 | H.P. ACTHAR | AC | 07/17/2013 | 5 | 07/30/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 51 | 63004871001 | H.P. ACTHAR | AC | 08/20/2013 | 5 | 09/04/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 52 | 63004871001 | H.P. ACTHAR | AC | 09/04/2013 | 5 | 09/19/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 53 | 63004871001 | H.P. ACTHAR | AC | 09/24/2013 | 5 | 10/03/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 54 | 63004871001 | H.P. ACTHAR | AC | 10/10/2013 | 5 | 10/21/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |

| Sample False Claim No. | NDC Code | NDC Code Description | Bene Name | Date From Claim | Units Quan Disp | Date Processed | Amt Above OOPT | Amt Below OOPT | Pharm ID | Presc ID |
|---|---|---|---|---|---|---|---|---|---|---|
| 55 | 63004871001 | H.P. ACTHAR | AC | 10/28/2013 | 5 | 11/13/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 56 | 63004871001 | H.P. ACTHAR | AC | 11/13/2013 | 5 | 12/02/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 57 | 63004871001 | H.P. ACTHAR | AC | 12/04/2013 | 5 | 12/11/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 58 | 63004871001 | H.P. ACTHAR | AC | 12/20/2013 | 5 | 01/01/2014 | $ 31,583.19 | $ - | Pharmacy 3 | MD 03 |
| 59 | 63004871001 | H.P. ACTHAR | AC | 01/06/2014 | 5 | 03/05/2014 | $ 25,339.77 | $ 6,243.42 | Pharmacy 3 | MD 03 |
| 60 | 63004871001 | H.P. ACTHAR | AC | 01/22/2014 | 5 | 03/05/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 61 | 63004871001 | H.P. ACTHAR | AC | 02/05/2014 | 5 | 03/05/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 62 | 63004871001 | H.P. ACTHAR | AC | 02/24/2014 | 5 | 03/05/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 63 | 63004871001 | H.P. ACTHAR | AC | 03/13/2014 | 5 | 03/19/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 64 | 63004871001 | H.P. ACTHAR | AC | 04/02/2014 | 5 | 04/17/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 65 | 63004871001 | H.P. ACTHAR | AC | 04/21/2014 | 5 | 04/30/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 66 | 63004871001 | H.P. ACTHAR | AC | 05/05/2014 | 5 | 05/15/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 67 | 63004871001 | H.P. ACTHAR | AC | 05/21/2014 | 5 | 05/28/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 68 | 63004871001 | H.P. ACTHAR | AC | 06/09/2014 | 5 | 06/26/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 69 | 63004871001 | H.P. ACTHAR | AC | 06/30/2014 | 5 | 07/23/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 70 | 63004871001 | H.P. ACTHAR | AC | 07/17/2014 | 5 | 07/25/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 71 | 63004871001 | H.P. ACTHAR | AC | 08/04/2014 | 5 | 08/25/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 72 | 63004871001 | H.P. ACTHAR | AC | 08/18/2014 | 5 | 09/03/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 73 | 63004871001 | H.P. ACTHAR | AC | 09/08/2014 | 5 | 09/18/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 74 | 63004871001 | H.P. ACTHAR | AC | 09/29/2014 | 5 | 10/16/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 75 | 63004871001 | H.P. ACTHAR | AC | 10/14/2014 | 5 | 10/29/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 76 | 63004871001 | H.P. ACTHAR | AC | 10/29/2014 | 5 | 11/12/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 77 | 63004871001 | H.P. ACTHAR | AC | 11/17/2014 | 5 | 11/26/2014 | $ 33,162.34 | $ - | Pharmacy 3 | MD 03 |
| 78 | 63004871001 | H.P. ACTHAR | AC | 12/03/2014 | 5 | 12/10/2014 | $ 33,162.34 | $ - | Pharmacy 5 | MD 03 |
| 79 | 63004871001 | H.P. ACTHAR | AC | 12/29/2014 | 5 | 01/07/2015 | $ 33,827.13 | $ - | Pharmacy 5 | MD 03 |
| Totals | | | | | 400 | | $ 2,538,202.22 | $ 23,969.54 | | |

# EXHIBIT 2

| Sample False Claim No. | NDC Code | NDC Code Description | Bene Name | Date From Claim | Units Quan Disp | Date Processed | Amt Above OOPT | Amt Below OOPT | Pharm ID | Presc ID |
|---|---|---|---|---|---|---|---|---|---|---|
| 80 | 63004773101 | ACTHAR HP | BA | 11/01/2012 | 5 | 11/21/2012 | $ 29,403.15 | $ - | Pharmacy 2 | MD 15 |
| 81 | 63004871001 | H.P. ACTHAR | BB | 04/15/2013 | 5 | 05/01/2013 | $ 23,897.86 | $ 7,434.98 | Pharmacy 3 | MD 14 |
| 82 | 63004871001 | H.P. ACTHAR | BB | 04/29/2013 | 5 | 05/15/2013 | $ 31,332.84 | $ - | Pharmacy 3 | MD 14 |
| 83 | 63004871001 | H.P. ACTHAR | BB | 05/21/2013 | 5 | 05/29/2013 | $ 31,332.84 | $ - | Pharmacy 3 | MD 14 |
| 84 | 63004871001 | H.P. ACTHAR | BB | 06/07/2013 | 5 | 06/12/2013 | $ 31,332.84 | $ - | Pharmacy 3 | MD 14 |
| 85 | 63004871001 | H.P. ACTHAR | BB | 07/01/2013 | 5 | 07/27/2013 | $ 31,583.19 | $ - | Pharmacy 3 | MD 14 |
| 86 | 63004871001 | H.P. ACTHAR | BC | 08/29/2013 | 10 | 09/12/2013 | $ 55,054.21 | $ 2,776.19 | Pharmacy 2 | MD 10 |
| 87 | 63004871001 | H.P. ACTHAR | BC | 10/18/2013 | 10 | 10/30/2013 | $ 57,830.40 | $ - | Pharmacy 2 | MD 10 |
| 88 | 63004871001 | H.P. ACTHAR | BC | 12/04/2013 | 10 | 12/18/2013 | $ 57,830.40 | $ - | Pharmacy 2 | MD 10 |
| 89 | 63004871001 | H.P. ACTHAR | BD | 05/30/2013 | 5 | 06/17/2013 | $ 27,191.80 | $ 3,287.08 | Pharmacy 2 | MD 11 |
| 90 | 63004871001 | H.P. ACTHAR | BE | 07/15/2013 | 5 | 07/29/2013 | $ 22,893.36 | $ 6,474.84 | Pharmacy 3 | MD 13 |
| 91 | 63004871001 | H.P. ACTHAR | BE | 12/05/2013 | 5 | 12/09/2013 | $ 29,368.20 | $ - | Pharmacy 3 | MD 13 |
| 92 | 63004871001 | H.P. ACTHAR | BE | 12/10/2013 | 5 | 12/16/2013 | $ 29,368.20 | $ - | Pharmacy 3 | MD 13 |
| 93 | 63004871001 | H.P. ACTHAR | BE | 12/16/2013 | 5 | 12/23/2013 | $ 29,368.20 | $ - | Pharmacy 3 | MD 13 |
| 94 | 63004871001 | H.P. ACTHAR | BE | 12/27/2013 | 5 | 12/30/2013 | $ 29,368.20 | $ - | Pharmacy 3 | MD 13 |
| 95 | 63004773101 | ACTHAR HP | BF | 10/25/2012 | 10 | 11/01/2012 | $ 57,485.10 | $ 5,181.18 | Pharmacy 4 | MD 18 |
| 96 | 63004773101 | ACTHAR HP | BF | 12/03/2012 | 10 | 12/12/2012 | $ 62,666.28 | $ - | Pharmacy 4 | MD 18 |
| 97 | 63004871001 | H.P. ACTHAR | BF | 03/05/2013 | 10 | 03/20/2013 | $ 56,735.03 | $ 5,931.25 | Pharmacy 4 | MD 18 |
| 98 | 63004871001 | H.P. ACTHAR | BF | 04/08/2013 | 10 | 04/17/2013 | $ 62,666.28 | $ - | Pharmacy 4 | MD 18 |
| 99 | 63004871001 | H.P. ACTHAR | BF | 07/15/2013 | 5 | 07/30/2013 | $ 31,583.99 | $ - | Pharmacy 4 | MD 18 |
| 100 | 63004871001 | H.P. ACTHAR | BF | 09/24/2013 | 5 | 10/03/2013 | $ 31,583.99 | $ - | Pharmacy 1 | MD 18 |
| 101 | 63004871001 | H.P. ACTHAR | BF | 10/22/2013 | 5 | 12/02/2013 | $ 31,583.29 | $ - | Pharmacy 4 | MD 18 |
| 102 | 63004871001 | H.P. ACTHAR | BF | 12/23/2013 | 5 | 01/08/2014 | $ 31,583.19 | $ - | Pharmacy 3 | MD 18 |
| 103 | 63004773101 | ACTHAR HP | BG | 09/25/2012 | 10 | 10/04/2012 | $ 53,041.52 | $ 6,124.61 | Pharmacy 4 | MD 18 |
| 104 | 63004871001 | H.P. ACTHAR | BH | 12/11/2013 | 5 | 01/01/2014 | $ 24,910.00 | $ 6,673.19 | Pharmacy 3 | MD 17 |
| 105 | 63004773101 | ACTHAR HP | BI | 08/03/2011 | 5 | 08/12/2011 | $ 26,294.41 | $ - | Pharmacy 6 | MD 21 |
| 106 | 63004773101 | ACTHAR HP | BI | 09/05/2011 | 5 | 09/12/2011 | $ 26,294.41 | $ - | Pharmacy 6 | MD 21 |
| 107 | 63004773101 | ACTHAR HP | BI | 10/07/2011 | 5 | 10/18/2011 | $ 26,294.33 | $ - | Pharmacy 6 | MD 21 |
| 108 | 63004773101 | ACTHAR HP | BI | 11/05/2011 | 5 | 11/10/2011 | $ 26,294.33 | $ - | Pharmacy 6 | MD 21 |
| 109 | 63004773101 | ACTHAR HP | BI | 12/17/2011 | 5 | 12/27/2011 | $ 26,294.33 | $ - | Pharmacy 6 | MD 21 |
| 110 | 63004773101 | ACTHAR HP | BI | 05/03/2012 | 5 | 05/17/2012 | $ 28,003.00 | $ - | Pharmacy 6 | MD 12 |
| 111 | 63004871001 | H.P. ACTHAR | BI | 11/08/2013 | 5 | 11/11/2013 | $ 30,001.12 | $ - | Pharmacy 7 | MD 19 |
| 112 | 63004773101 | ACTHAR HP | BJ | 11/28/2012 | 10 | 12/21/2012 | $ 62,571.34 | $ - | Pharmacy 4 | MD 18 |
| 113 | 63004773101 | ACTHAR HP | BK | 02/27/2012 | 5 | 03/05/2012 | $ 28,003.00 | $ - | Pharmacy 2 | MD 23 |
| 114 | 63004871001 | H.P. ACTHAR | BL | 09/12/2013 | 5 | 10/14/2013 | $ 30,724.15 | $ - | Pharmacy 2 | MD 16 |
| 115 | 63004871001 | H.P. ACTHAR | BL | 09/26/2013 | 5 | 10/19/2013 | $ 30,724.15 | $ - | Pharmacy 2 | MD 16 |
| 116 | 63004871001 | H.P. ACTHAR | BL | 10/18/2013 | 5 | 11/12/2013 | $ 30,724.15 | $ - | Pharmacy 2 | MD 16 |
| 117 | 63004871001 | H.P. ACTHAR | BL | 11/12/2013 | 5 | 12/02/2013 | $ 30,724.15 | $ - | Pharmacy 2 | MD 16 |
| 118 | 63004871001 | H.P. ACTHAR | BL | 03/11/2014 | 5 | 03/24/2014 | $ 28,643.67 | $ 3,616.35 | Pharmacy 2 | MD 16 |
| 119 | 63004871001 | H.P. ACTHAR | BM | 11/05/2013 | 5 | 11/21/2013 | $ 25,418.26 | $ 5,454.74 | Pharmacy 2 | MD 20 |
| 120 | 63004871001 | H.P. ACTHAR | BM | 12/04/2013 | 5 | 12/23/2013 | $ 30,873.00 | $ - | Pharmacy 2 | MD 20 |
| 121 | 63004773101 | ACTHAR HP | BN | 08/20/2012 | 5 | 08/30/2012 | $ 28,761.00 | $ - | Pharmacy 2 | MD 22 |
| | | | | Totals | 255 | | $ 1,477,637.16 | $ 52,954.41 | | |

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# EXHIBIT 3

| Subsidy Date | Fund | Acthar Copay Subsidy Amount Paid for Claim | Corresponding Sample False Claim No. |
|---|---|---|---|
| 08/09/2012 | MS Acute Exacerbation | $ 1,564.36 | 1 |
| 10/03/2012 | MS Acute Exacerbation | $ 1,564.36 | 2 |
| 10/19/2012 | MS Acute Exacerbation | $ 1,564.36 | 3 |
| 11/13/2012 | MS Acute Exacerbation | $ 1,564.36 | 4 |
| 11/23/2012 | MS Acute Exacerbation | $ 1,564.36 | 5 |
| 12/28/2012 | MS Acute Exacerbation | $ 1,564.36 | 6 |
| 01/30/2013 | MS Acute Exacerbation | $ 2,417.71 | 7 |
| 02/26/2013 | MS Acute Exacerbation | $ 1,564.36 | 8 |
| 03/22/2013 | MS Acute Exacerbation | $ 1,564.36 | 9 |
| 04/26/2013 | MS Acute Exacerbation | $ 1,564.36 | 10 |
| 05/14/2013 | MS Acute Exacerbation | $ 1,564.36 | 11 |
| 06/14/2013 | MS Acute Exacerbation | $ 1,576.86 | 12 |
| 06/28/2013 | MS Acute Exacerbation | $ 3,153.64 | 13 |
| 07/29/2013 | MS Acute Exacerbation | $ 1,576.86 | 14 |
| 08/12/2013 | MS Acute Exacerbation | $ 1,558.79 | 15 |
| 09/04/2013 | MS Acute Exacerbation | $ 1,558.79 | 16 |
| 09/23/2013 | MS Acute Exacerbation | $ 1,558.79 | 17 |
| 10/21/2013 | MS Acute Exacerbation | $ 1,558.79 | 18 |
| 10/29/2013 | MS Acute Exacerbation | $ 1,558.79 | 19 |
| 11/04/2013 | MS Acute Exacerbation | $ 1,558.79 | 20 |
| 11/12/2013 | MS Acute Exacerbation | $ 1,558.79 | 21 |
| 12/02/2013 | MS Acute Exacerbation | $ 1,558.79 | 22 |
| 09/12/2013 | Lupus Exacerbation | $ 3,445.34 | 23 |
| 09/30/2013 | Lupus Exacerbation | $ 1,543.65 | 24 |
| 10/17/2013 | Lupus Exacerbation | $ 1,543.65 | 25 |
| 11/11/2013 | Lupus Exacerbation | $ 1,543.65 | 26 |
| 11/25/2013 | Lupus Exacerbation | $ 1,543.65 | 27 |
| 12/10/2013 | Lupus Exacerbation | $ 1,543.65 | 28 |
| 12/30/2013 | Lupus Exacerbation | $ 1,543.65 | 29 |
| 01/16/2014 | Lupus Exacerbation | $ 3,401.31 | 30 |
| 02/04/2014 | Lupus Exacerbation | $ 1,620.83 | 31 |
| 02/25/2014 | Lupus Exacerbation | $ 1,620.83 | 32 |
| 03/18/2014 | Lupus Exacerbation | $ 1,620.83 | 33 |
| 04/03/2014 | Lupus Exacerbation | $ 1,620.83 | 34 |
| 04/23/2014 | Lupus Exacerbation | $ 1,620.83 | 35 |
| 05/06/2014 | Lupus Exacerbation | $ 1,620.83 | 36 |
| 05/20/2014 | Lupus Exacerbation | $ 1,620.83 | 37 |
| 06/04/2014 | Lupus Exacerbation | $ 1,620.83 | 38 |
| 06/26/2014 | Lupus Exacerbation | $ 1,620.83 | 39 |
| 07/16/2014 | Lupus Exacerbation | $ 1,620.83 | 40 |
| 07/31/2014 | Lupus Exacerbation | $ 1,620.83 | 41 |
| 08/18/2014 | Lupus Exacerbation | $ 1,620.83 | 42 |
| 09/04/2014 | Lupus Exacerbation | $ 1,620.83 | 43 |
| 09/25/2014 | Lupus Exacerbation | $ 1,620.83 | 44 |
| 10/20/2014 | Lupus Exacerbation | $ 1,620.83 | 45 |
| 11/13/2014 | Lupus Exacerbation | $ 1,620.83 | 46 |
| 12/04/2014 | Lupus Exacerbation | $ 1,620.83 | 47 |
| 12/22/2014 | Lupus Exacerbation | $ 1,653.33 | 48 |
| 07/01/2013 | RA Exacerbation | $ 3,175.92 | 49 |
| 07/17/2013 | RA Exacerbation | $ 1,579.16 | 50 |
| 08/20/2013 | RA Exacerbation | $ 1,579.16 | 51 |
| 09/04/2013 | RA Exacerbation | $ 1,579.16 | 52 |
| 09/24/2013 | RA Exacerbation | $ 1,579.16 | 53 |
| 10/10/2013 | RA Exacerbation | $ 1,579.16 | 54 |
| 10/28/2013 | RA Exacerbation | $ 1,579.16 | 55 |

# EXHIBIT 4

| Subsidy Date | Fund | Acthar Copay Subsidy Amount Paid For Claim | Corresponding Sample False Claim No. |
|---|---|---|---|
| 11/01/2012 | MS Acute Exacerbation | $ 1,470.16 | 80 |
| 04/15/2013 | RA Exacerbation | $ 3,557.71 | 81 |
| 04/29/2013 | RA Exacerbation | $ 1,566.64 | 82 |
| 05/21/2013 | RA Exacerbation | $ 1,566.64 | 83 |
| 06/07/2013 | RA Exacerbation | $ 1,566.01 | 84 |
| 07/01/2013 | RA Exacerbation | $ 1,579.16 | 85 |
| 08/29/2013 | MS Acute Exacerbation | $ 4,071.39 | 86 |
| 10/18/2013 | MS Acute Exacerbation | $ 2,891.52 | 87 |
| 12/04/2013 | MS Acute Exacerbation | $ 2,891.52 | 88 |
| 05/30/2013 | RA Exacerbation | $ 2,920.96 | 89 |
| 07/15/2013 | MS Acute Exacerbation | $ 3,359.85 | 90 |
| 12/05/2013 | MS Acute Exacerbation | $ 1,468.41 | 91 |
| 12/10/2013 | MS Acute Exacerbation | $ 1,468.41 | 92 |
| 12/16/2013 | MS Acute Exacerbation | $ 1,468.41 | 93 |
| 12/27/2013 | MS Acute Exacerbation | $ 1,468.41 | 94 |
| 10/25/2012 | RA Exacerbation | $ 5,186.54 | 95 |
| 12/03/2012 | RA Exacerbation | $ 3,113.31 | 96 |
| 03/05/2013 | RA Exacerbation | $ 5,569.33 | 97 |
| 04/08/2013 | RA Exacerbation | $ 3,113.31 | 98 |
| 07/15/2013 | RA Exacerbation | $ 1,559.20 | 99 |
| 09/24/2013 | RA Exacerbation | $ 1,559.20 | 100 |
| 10/22/2013 | RA Exacerbation | $ 1,559.16 | 101 |
| 12/23/2013 | RA Exacerbation | $ 1,559.16 | 102 |
| 09/25/2012 | RA Exacerbation | $ 5,289.25 | 103 |
| 12/11/2013 | MS Acute Exacerbation | $ 3,464.47 | 104 |
| 08/03/2011 | MS Acute Exacerbation | $ 1,304.72 | 105 |
| 09/05/2011 | MS Acute Exacerbation | $ 1,304.72 | 106 |
| 10/07/2011 | MS Acute Exacerbation | $ 1,304.72 | 107 |
| 11/05/2011 | MS Acute Exacerbation | $ 1,304.72 | 108 |
| 12/17/2011 | MS Acute Exacerbation | $ 1,304.72 | 109 |
| 05/03/2012 | MS Acute Exacerbation | $ 1,400.15 | 110 |
| 11/08/2013 | MS Acute Exacerbation | $ 1,500.06 | 111 |
| 11/28/2012 | RA Exacerbation | $ 3,128.57 | 112 |
| 02/27/2012 | MS Acute Exacerbation | $ 1,400.15 | 113 |
| 09/12/2013 | RA Exacerbation | $ 1,536.20 | 114 |
| 09/26/2013 | RA Exacerbation | $ 1,536.20 | 115 |
| 10/18/2013 | RA Exacerbation | $ 1,536.20 | 116 |
| 11/12/2013 | RA Exacerbation | $ 1,536.20 | 117 |
| 03/11/2014 | RA Exacerbation | $ 3,142.71 | 118 |
| 11/05/2013 | RA Exacerbation | $ 3,607.87 | 119 |
| 12/04/2013 | RA Exacerbation | $ 1,543.65 | 120 |
| 08/20/2012 | MS Acute Exacerbation | $ 1,438.05 | 121 |
| **Totals** | | $ 95,117.74 | |